Efficiency Trade-Offs in Patent Litigation Settlements: Analysis Gone Astray?

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PATENTS ARE INTENDED to allow a patent holder to obtain monopoly profits. To have this effect, a patent must limit competition.[1] As a consequence of limited competition, valuable patents result in "static inefficiency"[2] because consumer welfare suffers from high monopoly prices. Valid patents may nonetheless be efficient in a "dynamic" sense[3] because the possibility of monopoly profits spurs incentives to develop new products.[4] Consequently, as recognized by

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1. Of course, not all patents give the patent holder market or monopoly power. This is the case when, for example, the patented good faces many close substitutes at prices equal to its marginal costs or when there is little or no consumer value of the patented good. This Article does not consider cases where a patent gives no market power because in those cases there will be no gains from a payment settlement and therefore no economic incentive to engage in such settlements.

2. "Static inefficiency" refers to the inefficient allocation of available resources at a given point in time.

3. "Dynamic efficiency" refers to the efficient allocation of available resources over a period of time.

4. Even this presumption is not without controversy. "If national patent laws did not exist, it would be difficult to make a conclusive case for introducing them[,] . . . and it is equally difficult to make a really conclusive case for abolishing them." EDITH T. PENROSE, THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM 40 (1951); *see also* Josh Lerner, *150 Years of Patent Protection*, 92 AM. ECON. REV. 221 (2002) (finding that strengthening a patent system did not significantly impact inventions); Richard C. Levin et al., *Appropriating the Returns to Industrial Research & Development*, 3 BROOKINGS PAPERS ON ECON. ACTIVITY 783 (1987) (finding that patents are not among the important means to appropriate returns to innovation, although the pharmaceutical industry may be the exception); Wesley M. Cohen et al., NAT'L BUREAU OF ECON. RESEARCH WORKING PAPER, PROTECTING THEIR INTELLECTUAL ASSETS: APPROPRIABILITY CONDITIONS AND WHY U.S. MANUFACTURING FIRMS PATENT (OR NOT) 7552 (2000), *at* http://www.nber.org/papers/w7552 (last accessed Oct. 10, 2004). Mariko Sakakibara & Lee Branstetter, *Do Stronger Patents Induce More Innovation? Evidence from the 1988 Japanese Patent Reform Laws*, 32 RAND J. ECON. 77 (2001), found only a

many courts, patents present an inherent trade-off between static inefficiency and dynamic efficiency.[5]

Disputes as to the legitimacy and scope of a patent frequently arise. Many recent cases in the pharmaceutical industry involve settlements of such disputes, which feature a payment from the patent holder to the challenger. Private patent settlement agreements including those involving cash payments may be presumed to increase the value of the patent to the patent holder and thereby to increase dynamic efficiency. Nonetheless, we here argue that a per se rule against patent litigation settlements involving a cash payment from the patent holder to the challenger will maximize economic efficiency. Part I begins by providing a brief overview of the economic nature and value, both private and social, of patent rights. Parts II through IV then consider the economic impact of patent litigation settlement agreements and demonstrate that payments from the patent holder to the challenger are contrary to efficient patent litigation settlements. Part V then demonstrates that a probabilistic analysis of patent rights is consistent with traditional burdens of proof. Finally, this Article discusses an alternative approach towards judging patent settlements in which the efficiency of patent settlements is based on the patent's "validity." This Article concludes that such an approach makes no economic sense.

I. The Economic Nature of a Patent

Economics provides little guidance to the determination of the optimal static-dynamic efficiency trade-off.[6] Regardless, Congress has

very small effect on research and development ("R&D") activity from expanding the scope of Japanese patents. Bronwyn H. Hall & Rosemarie Ham Ziedonis, *The Patent Paradox Revisited: An Empirical Study of Patenting in the U.S. Semiconductor Industry, 1979–1995*, 32 RAND J. ECON. 101 (2001), found that large patent portfolios were mainly of help in negotiating cross-licensing agreements but that patents had little impact on innovating activity.

5. *See* Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1307 (11th Cir. 2003) ("A suitable accommodation between antitrust law's free competition requirement and the patent regime's incentive system is required by the complementary objectives of [patent law and antitrust law]."); *In re* Ciprofloxacin Hydrochloride (Cipro) Antitrust Litig., 261 F. Supp. 2d 188, 255–57 (E.D.N.Y. 2003).

6. *See* JEAN TIROLE, THE THEORY OF INDUSTRIAL ORGANIZATION 399 (1988) ("The welfare analysis [of patents] is relatively complex, and more work is necessary before clear and applicable conclusions will be within reach.") ("The current theories are much too rudimentary to be realistic."); Tuomas Takalo, *On the Optimal Patent Policy*, 14 FINNISH ECON. PAPERS 33, 33 (2001) ("'Numerous attempts have been made to identify the optimal mix of patent breadth and patent life. Unfortunately, the range of contradictory results reported in literature is rather impressive.'" (citation omitted)); JEFFREY K. MACKIE-MASON, WHAT TO DO ABOUT UNILATERAL REFUSALS TO LICENSE 1 (2002), *available at* http://www-personal.

specified a set of laws, rules, and procedures governing the granting and use of patents.[7] In enacting these rules and procedures, Congress has implicitly balanced the trade-off between the static efficiency of competition and low prices against the dynamic efficiency of increased incentives to seek patentable innovations. A proper economic welfare analysis of patent rights must take as given the patent rules specified by Congress with the presumption that those rules properly and correctly balance static and dynamic efficiency.[8]

In granting procedural rights to a patent holder, Congress did not provide that a patent is conclusively presumed to be valid.[9] Rather, the ultimate validity and scope of a patent cannot be known until final resolution of such issues by the courts.[10] The patent owner is never certain of its "right" to exclude others from the use or sale of the patented invention.[11] Even if the patent owner has knowledge of an alleged infringement, the patent owner cannot seize allegedly infringing goods. Moreover, the patent holder may choose not to elicit governmental efforts to exclude an alleged infringer because the process is costly. Finally, and most importantly, when the patent holder does attempt to enforce its rights through the coercive power of the

umich.edu/~jmm/papers/doj-ftc-refusals-to-deal.pdf (last accessed Oct. 10, 2004) ("The optimal balance between innovation incentives and protection against static monopoly harm is not knowable to any reasonable degree of precision.").

7. *See* 35 U.S.C. §§ 1–376 (2000).

8. It is the details of the substantive and procedural rules, as interpreted by the courts, that determine the economic value of a patent holder's rights. *See* Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 392 (2003) ("[R]ules governing settlements affect what is truly meant by the patent grant itself. In fact, in many fast-moving industries, the rules governing patent litigation and settlements are arguably far more important to patentees than the single variable on which economists have traditionally focused, namely patent length.").

9. 35 U.S.C. § 282 ("A patent shall be presumed valid."). As stated by the Supreme Court: "The heart of [the patent owner's] legal monopoly is the right to invoke the State's power to prevent others from utilizing his discovery without his consent." Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 135 (1969); *see also* Magnivision, Inc. v. Bonneau Co., 115 F.3d 956, 960 (Fed. Cir. 1997) ("The validity of a patent is always subject to plenary challenge on its merits. A court may invalidate a patent on any substantive ground, whether or not that ground was considered by the patent examiner.").

10. Indeed, a recent Federal Trade Commission ("FTC") study found that in 73% of Hatch-Waxman cases, the generic manufacturer was found not to have infringed a valid patent. FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 13 (2002). A so-called "Hatch-Waxman case" is one brought pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 (1994)).

11. The courts have recognized the inherent uncertainty of patent rights. *See, e.g., In re* Ciprofloxacin Hydrochloride (Cipro) Antitrust Litig., 261 F. Supp. 2d 188, 208, 212, 251 (E.D.N.Y. 2003).

government, its efforts may result in a finding of patent invalidity or non-infringement.

Many patents granted by the patent office are subsequently invalidated by the courts.[12] The consequent vulnerability of a patent creates an incentive for potential competitors to challenge the patent's validity or infringe upon it. Thus, the patent rules themselves provide an economic incentive for potential infringers to seek a judicial finding of invalidity or non-infringement. This incentive is a result of the very process and rules by which a patent holder may seek to enforce its right to exclude.

The incentives to challenge patents are particularly strong in the case of pharmaceutical patents because the Hatch-Waxman Amendments provide additional rewards motivating such challenges.[13] In the Hatch-Waxman Act, Congress expressly strengthened the incentive to challenge a pharmaceutical patent by offering 180 days of exclusivity to the first generic manufacturer to file a new drug application under the Hatch-Waxman Amendment's abbreviated process.[14] As noted by Judge Trager in *In re Ciprofloxacin Hydrochloride (Cipro) Antitrust Litigation*,[15] the "impetus behind the Hatch-Waxman Amendments was 'to make available more low cost generic drugs.'"[16]

Prior to a final court resolution of the validity and scope of a patent, the uncertainty as to the exact rights possessed by a patent holder under the rules enacted by Congress implies that the expected profits from a patent are in practice necessarily less than the full monopoly profits with complete exclusion. This is because of the "discount" to the full monopoly profits for the likelihood that the patent is invalid or limited in scope. The presumption that Congress correctly balanced static and dynamic efficiency implies that it is this expected

12. *See* John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q. J. 185, 192 (1998); Kimberly A. Moore, *Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365, 392 (2000).

13. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 (1994)).

14. *In re Cipro*, 261 F. Supp. 2d at 204. The court stated:

> [T]he crux of plaintiffs' claim of a *per se* violation is that the challenged agreements allowed Barr to accept cash in exchange for an agreement to halt the process by which a court *would* make such a determination [of whether the patent is valid or invalid]—a process encouraged by the Hatch-Waxman Amendments and beneficial to consumers.

Id.; *see also* 21 U.S.C. § 355(j)(5)(B)(iv).

15. 261 F. Supp. 2d 188 (E.D.N.Y. 2003).

16. *In re Cipro*, 261 F. Supp. 2d at 192; *see also* Andrx Pharms. v. Biovail Corp. Int'l, 256 F.3d 799, 809 (D.C. Cir. 2001).

profit, which is less than the full monopoly profit that creates the proper and efficient innovation incentive. Similarly, the presumption that Congress correctly balanced static and dynamic efficiency implies that increases in the expected profit to a patent holder through private agreements with potential competitors creates inefficient innovation incentives.

II. The Evaluation of Efficient Settlements Should Not Include Dynamic Efficiency Impacts

Where there is a patent for which validity has not yet been determined, the patent holder and potential infringers or competitors will have an economic incentive to reach agreements settling patent disputes. Indeed, from the challenger's perspective, there is an incentive to create and settle a dispute, with the challenger agreeing not to compete in return for a share of the monopoly profit. This incentive exists because the profit from the patent absent competition will necessarily be greater than the total profit earned by a patent holder plus that earned by any producer of a substitute competing product.[17] Of course, the increase in profits from such a settlement is at the expense of consumer welfare because consumers pay higher prices due to the lack of competition. The ever-present incentive to perpetuate the monopoly profit at consumers' expense underlies the efficiency of antitrust limits to settlement of patent disputes.

A basic premise underlying economic analysis is that parties to a private agreement are better off than if they had not reached the agreement. Hence, in the context of patent settlement agreements, it can be assumed that the patent holder achieves an increase in the expected profit as a result of the settlement. Thus, as a consequence of limiting a challenge to the patent through a private settlement agreement, the patent holder increases its expected profit above that granted by the patent itself. This increase in profit does increase the incentive to innovate. However, because it is the expected profit from the patent that dictates the efficient incentive to innovate, such private agreements limiting patent challenges increase the profits beyond those granted by Congress and beyond those that are presumed

17. If the patent holder and the challenger each have sufficient and favorably biased expectations as to their respective likelihood of prevailing in litigation, the added profits from sharing of the monopoly profits may not be sufficient to overcome the differing expectations. These cases in which settlement is not possible are discussed further below.

necessary for the efficient encouragement of innovation.[18] Hence, private patent settlement agreements can be presumed to improperly favor dynamic over static efficiency. Therefore, based on the static-dynamic efficiency balancing that Congress is assumed to have "gotten right," private patent settlement agreements should be presumed inefficient. Any impacts on "R&D" incentives and dynamic efficiency from a patent settlement need not be "balanced" in judging the settlement because Congress has already correctly maximized the static versus dynamic trade-off in creating the patent rules and procedures.

Basic economic principles also imply that if it were costless to resolve the validity and substantive scope of patents through litigation, the "efficient" balancing of static costs and benefits would always require such resolution through the courts. This implication follows from the presumption that Congress set up the efficient rules to resolve such disputes. Therefore, if litigation were costless, economic efficiency would imply that private settlements of patent disputes that create any static inefficiency would not be allowed; rather, courts would decide all such matters.[19] Of course, resolution of patent validity through the courts is not costless. This implies that the costs of litigation, and only these costs, give rise to the possibility of efficient private settlements.[20] However, only if the costs of litigation exceed the expected consumer welfare increase from the possibility of increased competition if a patent is found invalid or not infringed can private settlement of a patent dispute be efficient.

Challenges to a patent's scope or validity have efficiency benefits since challenges may increase competition and lower prices. The system of patent rights designed by Congress that allows private challenges to those rights is congruent with the interests of consumers. Nonetheless, private patent settlement agreements can be desirable

18. Any change to the rules and procedures governing patent rights that increases the expected profits from patents will increase the incentive to invest in seeking patents. This applies equally to rules allowing or constraining private agreements to extend patents, private agreements to limit competition among patent holders, or private agreements to give up a patent challenge in return for a share of the monopoly profits from the patent. However, such impacts on patent investment decisions are inefficient because they allow profit beyond that of the "optimal" rules that have been set by Congress.

19. Costless resolution of patent disputes is equivalent to a situation in which each patent reaches instantaneous, final resolution in the courts on disputed issues. In such a case, there would be no uncertainty concerning the validity and scope of all patents and no procompetitive benefits from agreements settling the dispute or from any private extensions of the patent rights.

20. This implies that all interim settlements that do not dispose of the litigation are necessarily inefficient.

because the expected costs of resolving the dispute (litigation costs) may exceed any expected consumer gains from the litigation. However, it can be quite difficult to measure expected litigation costs or expected consumer welfare gains from litigation. Yet, frequently, the relative efficiency of settlements of patent disputes can be judged without such complete knowledge of expected litigation costs or expected consumer welfare benefits.

Consider, for example, an "early entry" settlement in which the patent settlement allows the challenger to enter the market prior to the expiration of the disputed patent. An early entry settlement is relatively efficient as compared to a cash payment settlement in which the challenger agrees not to enter the market for some period of time in exchange for a share of the patent holder's monopoly profits. Since settlements eliminate the litigation costs by resolving the litigation, the relative efficiency of these settlements can therefore be judged solely based on the consumer welfare benefits. An early entry settlement will result in increased competition and a distribution of settlement benefits to consumers that more closely mimic the consumer benefits that would be expected from the patent litigation rules and procedures enacted by Congress. Similarly, a patent settlement that licenses the challenger is relatively efficient compared to a cash payment settlement, as the license settlement allows some extent of generic competition and, thereby, passes on some of the gains from settlement to consumers.

It is also straightforward to conclude that a settlement that includes a payment from the patent holder to the challenger and an early entry or licensing agreement is generally economically inefficient.[21] The payment inclusion will likely result in the challenger accepting less favorable entry timing or a higher licensing fee than otherwise would be negotiated. This result is to the clear detriment of consumers and optimally balances static and dynamic efficiency as dictated by the rules and procedures established by Congress.

21. The exception to this is if a payment was necessary to reach a settlement and the cost of litigation exceeded the expected consumer benefits from the litigation. However, as we show below, this is not likely the case and the remote possibility of such a case does not alter the efficiency of a per se rule.

III. There Is No Legitimate Justification for Cash Payment Settlements

A. Exclusion Payments Are Not Needed to Settle Hatch-Waxman Pharmaceutical Patent Disputes

Patent litigation is undoubtedly very expensive. If lump sum payments were necessary or even frequently required for settlement of patent challenges, a policy preventing all lump sum settlements could prevent otherwise efficient settlements. The fact that lump sum payments may possibly be required to reach settlement in patent litigation cases underlies recent opposition to a per se treatment of payment settlements.[22] Marc Schildkraut seized on this possibility noting that

> there are conditions under which an explicit or implicit "reverse" payment is necessary to settle patent litigation. There may be a gap between the parties that prevents settlement. This gap may be the result of a difference in perceptions about the outcome of the litigation or a difference in risk preferences.[23]

Mr. Schildkraut bases his arguments on the formal analysis of Willig and Bigelow, who show that it is theoretically possible that a payment from the patent holder to the generic challenger may be required to reach a settlement.[24] However, neither Schildkraut nor Willig and Bigelow perform any analysis of the likelihood that such a payment is required for settlement.

Examples can be constructed in which a settlement requires a lump sum payment. Such examples, however, arise only under extreme and unlikely conditions so that the theoretic possibility that cash payments are needed to reach efficient settlements provides no practical justification for allowing such settlements. To demonstrate

22. *See, e.g.*, Yee W. Chin & Thomas G. Krattenmaker, *Antitrust Update*, 2 MERGERS & ACQUISITIONS 30, 38 (2001); Richard J. Gilbert & Willard K. Tom, *Is Innovation King at the Antitrust Agencies? The Intellectual Property Guidelines Five Years Later*, 69 ANTITRUST L.J. 43, 78 (2001); Thomas B. Leary, *Antitrust Issues in Settlement of Pharmaceutical Patent Disputes*, ANTITRUST HEALTH CARE CHRON., Winter 2001, at 2, 6–7; Kevin D. McDonald, *Patent Settlements and Payments that Flow the "Wrong" Way: The Early History of a Bad Idea*, ANTITRUST HEALTH CARE CHRON., Winter 2002, at 2, 3–4.

23. Marc Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1058 (2004). Mr. Schildkraut represented Schering-Plough in *In re Schering-Plough Corp.*, No. 9297, 2003 F.T.C. LEXIS 187 (Dec. 8, 2003).

24. Robert Willig & John Bigelow, *Antitrust Policy Towards Agreements that Settle Patent Litigation*, ANTITRUST BULL. (forthcoming 2004). This analysis was presented by Professor Willig in his testimony on behalf of Schering-Plough before the FTC in *In re Schering-Plough Corp.*

the irrelevance of the Willig-Bigelow-Schildraut cash payment necessity situation, consider a typical generic challenge in some detail.

Assume a patented brand-name product with current and expected future annual sales of $500 million is subject to a generic challenge to its patent validity, as illustrated in Table 1.[25] The remaining expected period of exclusivity under the patent is presumed to be three additional years if either an agreement is reached with the generic challenger or the patent is found valid by the court. In addition, assume a profit margin above production and marketing expenses of 60% for the brand-name product absent generic entry. Future profits are reduced to present value using a discount rate of 10%. These assumptions are summarized in Table 1 of the appendix.

As also shown in Table 1, with generic entry, the brand-name producer will expect to retain only 40% of its sales during the first six months of generic competition and 20% of the sales thereafter. The generic challenger will set a price of 70% of the brand during the first six months of its entry when it has exclusivity. With no marketing expenses, the generic will expect a profit margin of 90% of the initial brand price. Thereafter, the generic price will fall to 20% of the initial brand price and the generic challenger will share the market with subsequent entrants, capturing one-third of the generic sales. The litigation costs of the brand name and the generic are assumed to be $20 million each.

The final set of assumptions concern the brand-name firm's reaction to the entry of the generic. Substantial research and the facts of cases under litigation indicate that little or no price change is expected for the brand-name product.[26] Therefore, assume the brand-name price is not impacted by generic entry. However, post-generic entry, the benefits from market expansion or retention or both will mostly benefit the generic entrant; therefore, the brand-name firm facing generic competition is expected to, and typically does, substantially reduce its marketing expense. The particular assumptions used regarding the marketing efforts and the effects on the market size are detailed in Table 1. In essence, the marketing efforts are reduced pro-

25. The assumptions of this example are generally consistent with the various cases that the authors are familiar with. The details of the assumptions are relatively unimportant to the result that payments from the brand-name firm to the generic are generally not necessary to settle patent litigation. Table 1 is located in the appendix to this Article.

26. *See, e.g.*, Z. John Lu & William S. Comanor, *Strategic Pricing of New Pharmaceuticals*, REV. ECON. & STAT., Feb. 1998, at 108–09; *see generally* Steven N. Wiggins & Robert Maness, *Price Competition in Pharmaceuticals: The Case of Anti-Infectives*, 42 ECON. INQUIRY 247 (2004).

portionally to the reduced brand name share and the "average return" to the marketing efforts is 15%.[27]

The assumptions from Table 1 imply that the expected present value of the profits to the brand-name firm, absent the generic entry, is $782 million. Of course, the expected profits from litigation depend upon the expectations of the brand-name firm and of the generic as to the likelihood of winning the litigation. Settlement will be possible for all pairs of expectations in which the combined expected profits of the two firms from litigation are less than the profit under monopoly. Not surprisingly, settlement is expected unless the parties have extremely optimistic expectations about success compared to that of the other party. This is not surprising because the profits to the generic from entry are significantly less than the losses to the brand-name firm caused by the generic's entry. This profit gain from the perpetuation of the monopoly, plus the litigation costs, creates the joint profitability of a settlement unless the two parties' beliefs are widely divergent and optimistic relative to one another.

Consider now the case of a settlement by the brand name seller in which the generic is allowed to enter prior to the end of the three-year period of exclusivity absent the challenge.[28] Assume the expected market shares, prices, and marketing efforts correspond to those under a six-month exclusive generic entry if a patent challenge were successful.

Table 2 summarizes the results of the analysis. Table 2 first shows the maximum expectations of prevailing in the patent litigation for the generic firm, given the expectations of the brand-name firm, which makes both a cash payment settlement possible and an early entry settlement possible. The first case is one in which the brand-name firm is certain that it will prevail. In this case, settlement will be possible only if the generic expects that its chances of prevailing are 56% or less. As also shown in the table, an early entry settlement will also be possible if the generic expects a 41% or less chance of winning the litigation. If the brand-name firm has an expectation of winning of 94% or less, settlement is possible regardless of the generic firm's ex-

27. Reasonable changes to these particular assumptions change no conclusions.

28. In earlier research, a model of licensing under somewhat different parameters than used here was considered. *See generally* 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 (2004) [hereinafter Leffler & Leffler, *Settling the Controversy*]. The essential findings were the same as found here—cash payments are rarely if even needed to settle patent challenges, and the cases in which such payments are required occur only in unreasonable and unrealistic situations. *Id.* at 477–85.

pectations. Also, as shown in Table 2, an early entry settlement, without any cash payment to the generic, will be possible as long as the brand-name firm has an expectation of winning of 91% or less. Thus, even with these outlandishly divergent expectations, cash payments are necessary to reach an efficient settlement only when the brand-name firm's expectation of winning is greater than 91%.[29]

The lower portion of Table 2 shows the maximum expectations of prevailing in the patent litigation for the brand firm, given the expectations of the generic firm, which makes a cash payment settlement possible and also for which an early entry settlement is possible. The first case is one in which the generic firm is "certain" that it will prevail. In this case, a settlement will be possible only if the brand-name firm expects that its chances of prevailing are 94% or less; an early entry settlement will also be possible as long as the brand firm expects a 91% or less chance of winning the litigation.

The implication of this analysis is that it is extremely unlikely that cash payments are needed for settlement of patent cases. Substantial research has been conducted regarding the likely results of patent litigation.[30] The results indicate that over one-half of all challenged patents are found invalid. Hence, it is not expected that a brand-name firm would have an expectation as high as 91% that it will prevail in a patent challenge. The analysis summarized in Table 2 indicates that even for unrealistic expectations of winning substantially above 70% by the brand-name firm, regardless of the generic firm's expectations, settlements without cash payments will generally be possible. In addition, while firms may have somewhat different expectations as to the outcome of patent litigation, the narrow range of wildly divergent expectations required to make cash payment settlements necessary for settlement are simply not expected to occur.

Therefore, we reach the conclusion that the theoretical possibility that cash payments are necessary to settle patent litigation, noted in our early research and more recently emphasized by authors supporting such settlements, while perhaps of academic interest, is of no relevance to a proper evaluation of the competitive or efficiency impact of these settlements. This is particularly significant when it is recognized that litigants will always prefer cash payment settlements because such settlements will eliminate the sharing in the gains of the patent challenge by consumers. For example, even if both the patent

29. Table 2 is available in the appendix to this Article.

30. *See, e.g.*, Allison & Lemley, *supra* note 12.

holder and the challenger are certain that the patent is invalid, settlement will be jointly profitable because a cash payment settlement will perpetuate the monopoly profits, which then may be divided among the brand-name firm and the generic. Hence, if cash payment settlements are allowed in all those cases in which a procompetitive settlement would otherwise be reached (which is likely to be all cases), competition will be limited. Therefore, cash payment settlements are anticompetitive and should not be allowed.

In contrast to the privately preferred exclusionary payment settlement, settling a patent dispute via a licensing agreement is inherently different in its competitive impact. A licensing agreement is of value to a patent challenger only because it allows the challenger to enter the market in competition with the patent holder. The economic expectation is that the licensee will take sales from the patent holder by offering more favorable prices. Hence, a license settlement agreement offers an alternative method to litigation by which lower cost drugs can be made available to consumers. Unlike payments to remain off the market, a licensing settlement transfers some of the benefits of a settlement to consumers. Thus, a licensing settlement is always preferred on an efficiency basis to a settlement that perpetuates the monopoly.

The approach taken here in evaluating the inefficiency of a payment settlement agreement is like that undertaken by the Federal Trade Commission ("FTC") in *In re Schering-Plough.*[31] There, the FTC noted that "there are likely to be efficiencies associated with the settlement of patent disputes between pioneer and generic manufacturers. A settlement can save public and private resources that would otherwise be consumed by the litigation . . . ."[32]

The FTC's analysis explored how the generic will settle only if it expects profits from the settlement at least equal to those expected from litigation. Thus, the efficiency issue in evaluating a payment settlement "is whether these unconditional payments were likely to have anticompetitive effects because they delayed generic entry beyond the dates that would have been agreed upon in the absence of the payments."[33]

The FTC focused on how settlements can be efficient by saving litigation costs while taking into account that efficient settlements recognize consumers' interest by generating some competition. The FTC

31. No. 9297, 2003 F.T.C. LEXIS 187 (Dec. 8, 2003).
32. *Id.* at *81–*82 (citations omitted).
33. *Id.* at *22.

concluded that the payment from the brand-name company to delay generic entry was unlawful because it eliminated the generic challenger's incentive to press for an earlier entry date.[34]

As the foregoing analysis demonstrates, cash payments from the brand-name company are presumably exclusionary. The greater the cash payment in the settlement, the lower the profits from competition that the generic will insist on. The greater the cash payments, the later the licensing entry date or the higher the royalty that will be acceptable to the generic. Hence, significant payments from the patent holder to the challenger push the settlement in the direction of a more anticompetitive and more inefficient outcome. This results in consumers being deprived of the expected gains from patent challenges that are granted them by the rules and procedures enacted by Congress that define the patent rights.

B. The Benefits of Generic Patent Challenges Will Not Be Reduced by Disallowing Cash Payment Settlements

One court has suggested that a possible benefit of allowing cash payment settlements is an increased incentive for generics to challenge patents.[35] However, on closer examination, this suggestion has no merit.

A patent challenge in and of itself is of no benefit. Generic challenges to patents under Hatch-Waxman are of value only because such challenges lead to increases in expected competition and, thereby, to lower consumer prices. Thus, challenges that are successful, either because of a court finding of invalidity or non-infringement or because of a licensing settlement agreement, are of value because they are procompetitive.

If exclusionary cash payment settlements are allowed, those challenges will result in no increase in competition; moreover, those challenges that would have settled with competition-enhancing licensing settlements will also likely conclude with an anticompetitive exclusionary cash payment settlement. This is, of course, contrary to the intent and purpose of the patent challenge incentives provided under Hatch-Waxman.[36] This inconsistency with the purposes of Hatch-Waxman further support the position that the patent rules and procedures

34. *Id.* at *182–*83.

35. Asahi Glass Co. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003).

36. *See* Keith Leffler & Cristofer Leffler, *The Probabilistic Nature of Patent Rights: In Response to Kevin McDonald*, 17 ANTITRUST 77, 80 (2003) [hereinafter Leffler & Leffler, *Patent Rights*].

enacted by Congress do not allow for private agreements to extend the value of patents via cash payments that result in a sharing of the monopoly profit between the patent holder and the challenger.

IV. Exclusionary Payment Settlements Likely Have Insignificant Impacts on Patenting Activity

Absent transaction costs, the optimal set of rights accompanying any particular innovation would certainly be specific to the innovation. For example, successful innovation that was the result of happenstance would receive little or no protection because such protection would not impact dynamic efficiency. In contrast, innovations with large social benefits but relatively low private benefits (such as an antibiotic that is resistant to bacteria mutations) would receive very strong protection. However, given the very high costs of specifying unique patent rights and procedures for particular innovations, Congress has created a simplified and presumptively efficient set of rights.

Undoubtedly, there may be cases in which a patent holder could show that extending the patent rights in a particular set of circumstances is, on net, efficient because the increase in dynamic efficiency in that set of circumstances outweighs the static inefficiency. Yet, the costs of such innovation-specific rule-making presumably outweigh any efficiency gains. Economically, a cash payment settlement agreement is simply a private agreement that increases the economic value of a patent beyond the value inherent in the patent rules enacted by Congress. If situation-specific welfare analysis can justify such private agreements extending the rights of a patent beyond those granted by the laws and procedures enacted by Congress, then the same logic would justify consumer-based challenges to the exercise of the standard rights granted by Congress when those rights imply net static inefficiency. If the rules and procedures enacted by Congress can be challenged by demonstrations balancing static and dynamic efficiency in a particular case, then the same logic would, for example, permit consumers to demonstrate that in a particular instance a twenty-year patent is too long, i.e., not optimal.

However, the balancing of static and dynamic efficiency is difficult, subject to substantial uncertainty, and expensive. Just as consumer challenges to the length of a patent are not allowed regardless of whether one can demonstrate the inefficiency of the patent length in a particular case, private alterations of the other rights granted by Congress should be presumed inefficient. The patent rights at issue in the Hatch-Waxman cases concern the inherent uncertainty of the va-

lidity or substantive scope of a patent that results from the rules and procedures enacted by Congress. Allowing private agreements that alter the uncertainty by eliminating competitive threats is economically no different than agreements to extend the temporal terms of the patent.

Disallowing cash payment settlements will reduce the average expected profits from a patent. It is reasonable to expect that any policy change that decreases the average profits from patent activities will decrease the incentive to engage in such activities.[37] However, noting the obvious fact that the cash payment settlements may increase expected innovation provides no more justification for such settlements than for any other private agreement that results in market exclusion.[38] The increased innovation is simply not relevant to the welfare evaluation. The resulting static inefficiency presumably outweighs the increased dynamic efficiency.

Nonetheless, some courts[39] have expressed concern as to innovation impacts of a per se approach to exclusion payment settlements.[40] However, economic principles and the experience of actual cases suggest little impact on innovation from disallowing exclusion payment settlements. The following propositions identify some economic fac-

37. This is distinct from a presumption that innovation will be reduced. The relationship between patents and innovation is not clear. Nonetheless, for the purposes of this discussion here, assume that allowing payments settlements that increase the expected returns from a patent would result in an increase in innovation.

38. *See, e.g.*, 12 HERBERT HOVENKAMP, ANTITRUST LAW ¶ 2043b1, at 237 (1999) ("[An] agree[ment] *not* to engage in a certain type of research and development should ordinarily be regarded as a naked output restriction in the market for new innovations, and thus should be illegal per se."); 4 JULIAN O. VON KALINOWSKI ET AL., ANTITRUST LAWS AND TRADE REGULATION § 73.02 (2d ed. 2004) ("Per se liability will flow from a horizontal agreement among competitors to suppress the use of patents for purposes of restraining trade."); Engine Specialties, Inc. v. Bombardier Ltd., 605 F.2d 1, 11 (1st Cir. 1979) (finding an agreement not to market product in development was per se unlawful); Discovision v. Disc Mfg., Inc., No. 95-345-SLR, 1997 U.S. Dist. LEXIS 7507, at *37–*39 (D. Del. Apr. 3, 1997) (stating that an agreement that "'essentially eliminated' the horizontal competitors' 'incentive to innovate and design around' [defendant's] patents" is per se unlawful).

39. *See In re* Terazosin Hydrochloride Antitrust Litig., 164 F. Supp. 2d 1340, 1349–50 (S.D. Fla. 2000). In *Cipro*, the court concluded that "when patents are involved, . . . the exclusionary effect of the patent must be considered before making any determination as to whether the alleged restraint is per se illegal." *In re* Ciprofloxacin Hydrochloride (Cipro) Antitrust Litig., 261 F. Supp. 2d 188, 249 (E.D.N.Y. 2003). The court ruled that the proper analysis requires balancing "the anticompetitive effects of the Settlement Agreements . . . against the benefits of allowing brand-name drug companies to invest in R&D with some degree of confidence that they will be able to control patent litigation risk." *Id.* at 257.

40. A "per se approach" refers to lump sum payment settlements being per se invalid.

tors that are relevant when evaluating the likely innovative impacts of disallowing cash payment settlements:

- Settlements that do not reduce litigation costs should be disallowed.
- The larger the monopoly returns received by the patent holder prior to a settlement, the smaller the impact from competition (absent the settlement agreement) on dynamic efficiency. This follows from the increased likelihood that the patent holder has collected profit prior to the agreement sufficient to motivate the innovative effort.
- The greater the number of potential challengers to the patent holder, the smaller the expected impact on static inefficiency loss from a settlement. This follows from the expectation that other challengers will limit any static inefficiency regardless of the particular settlement.
- The smaller the R&D investment necessary to obtain the patent, the smaller any impact on dynamic efficiency from competition absent the settlement.
- The smaller the consumer benefits from the patent innovation, the smaller any impact on dynamic efficiency from allowing competition. Dynamic efficiency results from the expected consumer surplus from a new product that would not have been produced absent the patent. Innovations that yield little or no additional consumer surplus do not increase dynamic efficiency.
- The greater the likelihood that the patent holder could collect the damages from infringement, the smaller any impact on dynamic efficiency from allowing competition. Dynamic efficiency losses occur only because of profit reductions resulting from competition. If infringement damages are collectible, there can be no adverse impact on dynamic efficiency.

To understand the application of these propositions, presume that the rules judging the legality of a firm's exclusionary cash payment settlement take into account the likely impact on the firm's incentive to engage in the R&D efforts that lead to new pharmaceuticals if the firm had known that the cash payment settlement would not be allowed in certain circumstances. The propositions imply, for example, that agreements that occur only after significant monopoly profits have been earned will be disfavored. Similarly, agreements that adversely impact the cost of entry of others outside the agreement will be disfavored, as will agreements that involve the only likely patent challenger. In contrast, if the agreement occurs with a payment less than the expected litigation costs, or if the agreement concerns a challenging firm with little or no resources to enter, the agreement will more likely be found legal.

The propositions outlined above are intended to impact firms, ex ante R&D decisions. Thus, for example, if a company engaged in R&D

knows that payment settlement agreements will be disallowed when those agreements are made after significant monopoly profits have been earned, the impact on R&D investment decisions and on dynamic efficiency will be minimal. If, however, such agreements are disallowed prior to the earning of significant profits from the R&D investments, more significant impacts will result. The other propositions should be interpreted similarly.[41]

Application of these principles can be illustrated from the facts of *In re Terazosin Hydrochloride Antitrust Litigation*,[42] a case dealing with Abbott's patents of terazosin hydrochloride, which Abbott marketed under the brand name Hytrin.[43] In 1977 and 1978, Abbott was granted the '894 and '097 patents on Hytrin, respectively.[44] These patents gave Abbott a monopoly on the sale of the terazosin hydrochloride molecule until the patents expired in 1994 and 1995.[45] Thus, Abbott fully exploited its patent rights under these patents in its marketing of Hytrin. Abbott received its '207 patent in 1996.[46] This patent covered a Form IV anhydrous version of Hytrin.[47] Abbott sued the generic ANDA filers[48] of capsule forms of terazosin hydrochloride for infringement of this patent.[49] However, Abbott never marketed a pharmaceutical using the '207 patent. Hence, no therapeutic advantages or innovation important to consumers resulted from this patent, and therefore, no apparent increase in dynamic efficiency resulted from the '207 patent.[50] The '207 patent did have value because it effectively extended Abbott's Hytrin monopoly. Because of the '207 patent, under FDA rules, generic manufacturers making an anhydrous

41. As another example, consider the proposition that the smaller the consumer benefits from the patent innovation, the smaller any impact on dynamic efficiency from allowing competition. This proposition should be interpreted as implying that disallowing payment agreements for patents that provide small consumer benefits will have less impact on dynamic efficiency than disallowing such agreements for patents related to socially important innovation.

42. 164 F. Supp. 2d 1340 (S.D. Fla. 2000).

43. *Id.* at 1340.

44. *In re* Terazosin Hydrochloride Antitrust Litig., No. 99-MDL-1317, 2004 U.S. Dist. LEXIS 17518, at *14–*16 (S.D. Fla. June 23, 2004).

45. *Id.* at *15–*16. Abbott also received a patent on a dihydrate form of terazosin in 1981. *Id.* at *17.

46. *Id.* at *18.

47. *Id.*

48. An "ANDA filer" is a party who has filed an Abbreviated New Drug Application. *In re* Schering-Plough Corp., No. 9297, 2003 F.T.C. LEXIS 187, at *2 (Dec. 8, 2003).

49. *In re Terazosin*, 2004 U.S. Dist. LEXIS 17518, at *22–*32.

50. Innovation refers to some valuable *new* product (or process or method of production). The '207 patent was found to be invalid because the Form IV anhydrous version claimed was not new. *Id.* at *35. Therefore, the "patent" did not represent innovation.

form of Hytrin were required to file a Paragraph IV Certification, which led to an automatic thirty month delay in FDA approval. These facts imply that Abbott received substantial monopoly profits from Hytrin prior to its exclusionary settlements with the generic challengers, Geneva and Zenith.[51] Therefore, we suggest that there would have been little impact on Abbott's terazosin R&D had it known at the time of its investments that a cash payment settlement in the late 90s would not be legal. In addition, the disputed patent did not generate significant consumer benefit. Hence, according to the principles outlined above, the agreement should be disfavored on a dynamic efficiency basis.

On August 28, 1998, the district court ruled the '207 patent invalid,[52] and the appellate court upheld this ruling in July 1999.[53] There is a strong likelihood that, at the time of the decision, the district court ruling of invalidity was correct,[54] as district court decisions as to invalidity are usually upheld on appeal.[55] Thus, after the district court ruling of invalidity, there is little concern with any impacts on dynamic efficiency and innovation activity from any expected generic competition related to the '207 patent. Therefore, continued adherence to the settlement agreements after the patent had been held invalid should be disfavored.

51. In addition, a number of generic producers had filed ANDAs for a tablet form of Hytrin in the early 1990s in anticipation of the expiration of the '894 and '097 patents. In 1995, Abbott began marketing a capsule form of Hytrin, and Abbott converted nearly all Hytrin sales to the capsule form. The generics' tablet forms submitted for ANDAs would not have A-B rated FDA equivalence to Hytrin in its capsule form. This meant that pharmacists could not substitute the generic tablet for the Hytrin capsule without the prescribing physician's approval. As a result, the change to the capsule form effectively increased Abbott's monopoly profits from Hytrin beyond those of its initial patents without Abbott incurring significant additional R&D expenses.

52. Abbott Labs. v. Geneva Pharms. Inc., No. 96 C 3331, 1998 U.S. Dist. LEXIS 13864, at *24 (N.D. Ill. Aug. 28, 1998).

53. Abbott Labs. v. Geneva Pharms. Inc., 182 F.3d 1315, 1318 (Fed. Cir. 1999).

54. The number of generics challenging the '207 patent also provides evidence that the patent was likely invalid. *See In re Terazosin*, 2004 U.S. Dist. LEXIS 17518, at *32–*36.

55. *See, e.g.*, Allison & Lemley, *supra* note 12, at 241 tbl.15 (illustrating that of seventy-eight cases appealed from 1989 through 1996, 83.3% decisions of invalidity were affirmed); Moore, *supra* note 12, at 397 tbl.6 (stating that of 620 cases appealed from 1993 through 1998, 78% of district court decisions concerning validity were affirmed); FED. TRADE COMM'N, *supra* note 10, at 21 (explaining a study which found the rate at which the U.S. Court of Appeals for the Federal Circuit overturned district court decisions of patent invalidity for drug products to be 8%). The presumption that district court findings of invalidity are "accurate" is implicit in the use of the district court invalidity decision date for purposes of the 180-day exclusivity for the first ANDA filer. *See* Abbott Labs. v. Mylan Pharms., 37 F. Supp. 2d 1076, 1078 (N.D. Ill. 1999); TorPharm Inc., v. Shalala, No. 97-1925, 1997 U.S. Dist. LEXIS 21983, at *9–*12 (D.D.C. Sept. 15, 1997).

Under Hatch-Waxman, Geneva, the first ANDA filer, had a 180-day exclusive over the capsule version of a generic Hytrin. The period of exclusivity began only from the date of Geneva's marketing of the generic or from the time of a decision of invalidity. The Abbott-Geneva settlement agreement that delayed Geneva's marketing therefore not only delayed Geneva's entry decision, but it also impacted the incentive for other generics to aggressively challenge the Hytrin patent. Hence, in this case, Geneva was effectively the only challenger of the '207 patent. This factor would also support disfavoring this settlement agreement under the analysis of possible dynamic efficiency effects outlined above.[56]

V. A Probabilistic Analysis of Patents Is Consistent with Traditional Civil Burdens of Proof

The approach presented here is based on the fact that patent rights are probabilistic in nature.[57] The probability that a patent will be found to be invalid is what gives rise to the expected consumer benefits from a patent challenge. However, in a recent article, Marc Schildkraut argued that cash payment settlements should be allowed because any anticompetitive impact from the settlement is speculative due to its probabilistic nature. Schildkraut claims that "[u]ncertain competition analysis is a substantial departure from the traditional civil burdens of proof."[58] We believe Schildkraut's claim is incorrect.

The harmful effects of rejecting "probabilistic anticompetitive effects" under the Sherman Antitrust Act ("Sherman Act") are clear.[59] To illustrate, consider a hypothetical in which a firm has a monopoly over a product that is distributed throughout the United States. Assume another firm manages to make a perfect substitute for the product, but that this potential entrant has limited capacity and will be able to supply only 10% of the country. Prior to the entrant deciding where it would market the competing product, the incumbent and the potential entrant enter into an agreement in which the incumbent pays the potential entrant not to enter. In this situation, no consumer

56. Note also that the settlements in Hytrin did not resolve the patent litigation but rather only prevented generic entry prior to the conclusion of the litigation. Hence, in this case, the agreements resulted in little savings in litigation costs and therefore resulted in little or no gains in static efficiency. The settlement agreements were therefore clearly anticompetitive.

57. The probabilistic nature of all property rights is discussed at length in Leffler & Leffler, *Patent Rights*, *supra* note 36, at 77.

58. Schildkraut, *supra* note 23, at 1049.

59. 15 U.S.C. § 1 (2004).

could establish that it was harmed with certainty since there is only a 10% probability that the entry would have occurred in any particular place. However, following the Schildkraut approach, which requires certainty rather than probability, no plaintiff could bring an action against such a clearly anticompetitive agreement.

Fortunately, a recent case, *United States v. Microsoft Corp.*,[60] demonstrates that the elimination of uncertain competitive benefits is unlawful under the Sherman Act.[61] In *Microsoft*, the Department of Justice alleged that Microsoft unlawfully maintained its operating system monopoly by foreclosing Netscape's and Java's distribution channels. Microsoft countered that there could be no finding that it had violated the Sherman Act absent proof that the Netscape or Java products, which were only in developmental stages, would in fact have developed into commercially viable products.[62] The court of appeals rejected that contention because "[t]o require that [Sherman Act] liability turn on a plaintiff's ability or inability to reconstruct the hypothetical marketplace absent a defendant's anticompetitive conduct would only encourage monopolists to take more and earlier anticompetitive action."[63] The court held that exclusionary conduct is unlawful when it

> is aimed at producers of nascent competitive technologies as well as when it is aimed at producers of established substitutes. Admittedly, in the former case there is added uncertainty, in-as-much as nascent threats are merely *potential* substitutes. But the underlying proof problem is the same—neither plaintiffs nor the court can confidently reconstruct a product's hypothetical technological development in a world absent the defendant's exclusionary conduct.[64]

Thus, under the Sherman Act, a plaintiff could show an anticompetitive impact without showing that the Netscape and Java products "would actually have developed into viable platform substitutes."[65] Rather, the plaintiff need only show that "as a general matter the exclusion of nascent threats is the type of conduct that is reasonably capable of contributing significantly to a defendant's continued monopoly power."[66] "[R]easonably capable of contributing to a defendant's continued monopoly power" may be interpreted to mean a

60. 253 F.3d 34 (D.C. Cir. 2001).
61. *Id.* at 78.
62. *Id.* at 78–79.
63. *Id.* at 79.
64. *Id.*
65. *Id.*
66. *Id.*

reasonable probability that the alleged illegal behavior reduces consumer welfare.

Similarly, in *Microbix Biosystems, Inc. v. Biowhittaker, Inc.*,[67] the court held that a plaintiff could establish a violation of the rule of reason even though subsequent conduct implied that no one was in fact harmed by the defendant's conduct.[68] In *Microbix*, a brand-name pharmaceutical manufacturer entered into an exclusive supply agreement with a firm that was the only source of a key input, thus denying the input to generic manufacturers.[69] The court held that if the plaintiff could establish the facts alleged, "the anti-competitive effects of the exclusive agreement would be obvious."[70] The court reached that conclusion even though the plaintiff's theory of causation required it to show "that Plaintiff would have successfully secured a manufacturing facility, obtained FDA approval, developed the [product] in commercial quantities, and marketed the product during the relevant time frame."[71] Indeed, although the court entered summary judgment against the plaintiff on the causation question,[72] the court nevertheless held that the facts alleged as to liability stated a cause of action.[73]

These cases firmly establish that it is anticompetitive for an incumbent manufacturer to enter into an agreement to eliminate potential competition, based on the probability that the competition would in fact have occurred.[74] Indeed, a leading antitrust treatise addressing this issue notes that "the law does not condone the purchaser of protection from uncertain competition any more than it condones the elimination of actual competition."[75]

67. 172 F. Supp. 2d 680 (D. Md. 2000).

68. *Id.* at 692–94.

69. *Id.* at 692.

70. *Id.*

71. *Id.* at 698.

72. This was because the evidence showed that these tasks would not in fact have been completed before other intervening events—including an FDA ban on the importation of the product—severed the chain of causation. *Id.*

73. *Id.*

74. *See, e.g.*, Andrx Pharms., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 806–07 (D.C. Cir. 2001); Engine Specialties, Inc. v. Bombardier Ltd., 605 F.2d 1, 9 (1st Cir. 1979) (holding that it is unlawful to agree to suppress a product of which only a prototype had been made); Eli Lilly & Co. v. Zenith Goldline Pharms., Inc., 172 F. Supp. 2d 1060, 1075 (S.D. Ind. 2001) ("Potential competitors cannot stifle nascent competition by entering into an agreement restraining trade.").

75. 12 HOVENKAMP, *supra* note 38, ¶ 2030b, at 175.

VI. Concluding Remarks—Judging Patent Settlements Based on the Patent's Validity Makes No Economic Sense

We have argued that basic economic and logic principles imply that patent settlements between competitors should be judged on a static basis and that static benefits from such settlements are limited to the cost of litigation.[76] Our argument implies that cash payment settlements should be judged illegal under a per se rule. While it is theoretically possible that settlement requires cash payments, such cases are of no practical relevance. We have also argued that when settlement is possible, consumers should be included in the benefits from settlement. Hence, this implies that settlements should be disfavored unless consumers receive benefits such as those expected if the litigation was pursued.[77] However, the expected static consumer benefit from litigation depends on the probability that the patent will be found to be valid. This has led some courts and commentators to suggest that the proper policy approach in judging these settlements should take into account the "actual" validity of the patent.[78]

Recently, Kevin McDonald has taken this approach a step further, arguing that the risk that a federal court adjudicating a patent dispute might erroneously conclude that a patent is invalid can cause sub-optimal investments in R&D, and accordingly, a patent holder should be permitted to pay a challenger to recognize the validity of the patent.[79] McDonald suggests that a proper resolution of the possibility of false positives is to require an antitrust plaintiff challenging the lawfulness of a lump sum settlement to establish in the antitrust litigation that the patent, in fact, is invalid.[80]

However, rather than promoting efficient settlements that reduce litigation costs, evaluating settlements based on the "validity" of the patents will increase the expected cost of litigation. Settling parties have no incentive to challenge their own settlement agreement; rather, any challenge to a patent settlement will likely be in an antitrust case brought by the purchasers of the patented product or by the government. Yet, these antitrust plaintiffs taking on the burden of demonstrating invalidity have to start from scratch and re-learn much

76. *See* Leffler & Leffler, *Settling the Controversy*, *supra* note 28, at 477–85.

77. This is also the view taken by Shapiro. *See* Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 396 (2003).

78. *See, e.g.*, Kevin McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On Probabilistic Patent Rights and False Positives*, ANTITRUST, Spring 2003, at 68.

79. *Id.* at 74–75.

80. *Id.*

of what the generic challenger likely knew before accepting the settlement. In addition, as antitrust plaintiffs, purchasers are likely to be at an information disadvantage compared to the generic challenger because the generic challenger is in the business of researching pharmaceuticals, understanding pharmaceutical patents, and assessing patent validity.

If patent settlements are judged on the basis of the patent validity, in addition to having the "wrong plaintiff" challenger, substantial time is likely to be lost between the resolution of the original patent dispute via settlement and resolution of the settlement challenge.[81] This substantial delay is problematic because, even if the antitrust plaintiffs ultimately prevail, damages do not rectify the harm to consumers done by the substantial delay in resolution. For example, in response to the high cost of pharmaceuticals, many consumers forego taking medicine or cut the prescribed doses.[82] This harm to consumers is not corrected in any form in an antitrust action.

Distilled to its essence, the view that the validity of cash payment settlements should rest upon the validity or invalidity of the patent implies that such settlements should generally be prohibited because they do not settle anything. The patent litigation is simply delayed, a disadvantaged plaintiff is substituted for the best plaintiff, and the cost of the litigation is increased.

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81. The time problem is well exemplified by ongoing litigation: in 1992, the Zeneca-ICI patent on tamoxifen was found to be invalid. *See In re* Tamoxifen Citrate Antitrust Litig., 277 F. Supp. 2d 121, 125 (E.D.N.Y. 2003). In 1993, Zeneca and Barr entered into a lump sum settlement agreement whereby Barr abandoned its patent challenge. *Id.* at 125. Seven years later, in 2000, private plaintiffs filed suit. *Id.* Eleven years after the agreement was entered, the case remains under appeal.

In August 1995, Upsher filed an ANDA for a generic version of Schering-Plough's K-Dur. *In re* Schering-Plough Corp., No. 9297, 2003 F.T.C. LEXIS 187 (Dec. 8, 2003). On June 17, 1997, the eve of litigation concerning the validity of Schering-Plough's patent, Upsher and Schering-Plough entered a settlement agreement with lump sum payments from Schering-Plough to Upsher. The settlement delayed generic entry until September 2001. The FTC and private litigants challenged the settlement. The FTC subsequently ruled on December 18, 2003 that the settlement agreement was illegal and anticompetitive. However, that decision has been appealed and neither the FTC's case nor the private cases are resolved more than seven years after the settlement agreement.

In 1991, Barr challenged Bayer's patent on Cipro. *In re* Ciprofloxacin Hydrochloride (Cipro) Antitrust Litig., 261 F. Supp. 2d 188 (E.D.N.Y. 2003). The trial on the validity of the patent was scheduled to begin in January of 1997. At that time, Bayer and Barr entered into settlement agreements in which Barr withdrew its challenge. As part of the agreements, Bayer made substantial payments to Barr. *Id.* at 195–96. Private cases alleging the agreements to be illegal were filed and have yet to be tried.

82. *See* CLAUDIA L. SCHUR ET AL., LACK OF PRESCRIPTION COVERAGE AMONG THE UNDER 65: A SYMPTOM OF UNDERINSURANCE 2 (2004); CTR. ON AN AGING SOC'Y, GEORGETOWN UNIV., DATA PROFILE NO. 5, PRESCRIPTION DRUGS: A VITAL COMPONENT OF HEALTHCARE 4 (2002).

Appendix

TABLE 1
Assumptions for Analysis of Need for Cash Payments to Achieve an Efficient Settlement

Annual Market Size (at Brand Price ("BP"))	$500 million
Expected Monopoly Period with Settlement	3 years
Generic Price with Exclusivity (%BP)	70%
Generic Price with Generic Competition (%BP)	20%
Brand Market Share with Generic Exclusivity	40%
Brand Market Share with Generic Competition	20%
Entrant Generic Market Share with Generic Competition	33%
Brand Variable Costs with Marketing (%BP)	40%
Brand Variable Costs with Reduced Marketing (%BP)	10%
Generic Variable Costs (%BP)	10%
Discount Rate	10%
Litigation Cost (each)	$20 million

TABLE 2
Expectations of Winning Patent Litigation for Which Settlement is Possible

Assumed Expectation of Brand Firm	Maximum Expectation for Generic Firm for Which Settlement Is Possible	
	With Cash Payment	With Early Entry License
100%	56%	41%
94%	100%	80%
<91.6%	100%	100%

Assumed Expectation of Generic Firm	Maximum Expectation for Brand Firm for Which Settlement Is Possible	
	With Cash Payment	With Early Entry License
100%	94%	91%
56%	100%	97%
<41.1%	100%	100%