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Commentary


Thomas F. Cotter†

I would like to thank the Minnesota Law Review for inviting me to comment on the article by Herbert Hovenkamp, Mark Janis, and Mark Lemley, entitled Anticompetitive Settlement of Intellectual Property Disputes.1 As these comments will show, I agree with most of the authors’ analysis. That analysis elaborates upon previous work by Professor Hovenkamp2 that I have cited with approval in the past.3 Moreover, the authors’ proposed framework for evaluating settlements involving what they refer to as “exclusion payments”4 from the plaintiff to the defendant is, as they acknowledge, “roughly comparable” to a framework I recently proposed.5 Part I of this Commentary explains why the authors’ general framework for evaluating settlements of intellectual property disputes is sound. Part II focuses more directly on settlements involving reverse payments, including a more detailed proposal than I have previously attempted...

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4. See Hovenkamp et al., supra note 1, at 1720.
5. See id. 1759 n.177.
regarding the nature of the antitrust defendants' burden in an action involving these payments.\textsuperscript{6} Part II also suggests some modifications to the authors' recommended solution to this particular problem. This Commentary concludes that while the approach to evaluating settlement agreements advocated by Hovenkamp, Janis, and Lemley is generally appropriate, courts should consider ways of further simplifying the analysis in the middle class of cases in which the legality of settlements between parties may depend upon the resolution of patent issues, especially when these settlements involve reverse payments.

\section*{I. THE GENERAL FRAMEWORK}

The general framework proposed by Hovenkamp, Janis, and Lemley builds upon Hovenkamp's previous work on the anticompetitive potential of settlements of intellectual property disputes. As the authors note, the settlement of intellectual property disputes implicates several policies that pull in different directions. On one hand, settlement is usually, though not universally, viewed as a social good because it reduces the private and social costs of litigation.\textsuperscript{7} Patent litigation in particular is traditionally very expensive, and thus these costs can be quite high.\textsuperscript{8} Moreover, at least some agreements that otherwise would be suspect or even clearly illegal under general principles of antitrust law, such as territorial market divisions, may be lawful as a matter of intellectual property (IP) law.\textsuperscript{9} This disparity arises from the

\begin{itemize}
\item \textsuperscript{6} I use the term "reverse payments," rather than "exclusion payments," because the payments go in the reverse direction from what one would assume is common, i.e., from plaintiff to defendant instead of from defendant to plaintiff.
\item \textsuperscript{7} See Hovenkamp et al., \textit{supra} note 1, at 1723; see also Blair & Cotter, \textit{supra} note 3, at 513 n.99 (citing literature on the advantages and disadvantages of settlement); Daniel A. Crane, \textit{Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications}, 54 \textit{FLA. L. REV.} 747, 752 (2002).
\item \textsuperscript{8} See Hovenkamp et al., \textit{supra} note 1, at 1723; see also Roger D. Blair & Thomas F. Cotter, \textit{The Elusive Logic of Standing Doctrine in Intellectual Property Law}, 74 \textit{TUL. L. REV.} 1323, 1363 n.187 (2000) (citing sources that discuss the costs associated with patent litigation); Crane, \textit{supra} note 7, at 757.
\item \textsuperscript{9} See Hovenkamp et al., \textit{supra} note 1, at 1720; see also 12 HOVENKAMP, \textit{supra} note 2, § 2040(b), at 201 n.10; 2 HERBERT HOVENKAMP ET AL., \textit{IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW} § 33.3(a) (2002); Blair & Cotter, \textit{supra} note 3,
\end{itemize}
fact that although both antitrust and IP law may be viewed as tools for enhancing consumer welfare, they do so in different ways: antitrust law by encouraging competition and discouraging monopoly, and IP law by discouraging certain forms of competition and facilitating some forms of monopoly.\textsuperscript{10} On the other hand, virtually any agreement between an IP rights (IPRs) owner and an alleged infringer has the potential for abuse, because (1) some, though not all, IPRs confer market power;\textsuperscript{11} (2) some, though not all, asserted IPRs are not properly enforceable, either as a general matter or against the alleged infringer in particular;\textsuperscript{12} and (3) some, though not all, agreements between a rights owner and an alleged defendant may facilitate the division of markets or other anticompetitive behavior beyond that which is contemplated by IP laws.\textsuperscript{13} Finally, as the authors note, in some instances the parties to an IPRs dispute settlement might have chosen a less restrictive alternative than the one they actually chose, such as a nonexclusive cross-license rather than a market division.\textsuperscript{14} The impact of these competing policies has been for courts to treat settlements of IP disputes with some deference,\textsuperscript{15} although this deference hardly equates to per se legality; indeed, some of the leading decisions involving unlawful restraints have involved agreements to settle IP disputes.\textsuperscript{16} Making sense of the various strands in the case law is thus no easy task.

Hovenkamp, Janis, and Lemley propose that courts can attempt to negotiate this difficult terrain by dividing the IP/antitrust cases involving dispute settlements into three classes. The first class consists of cases in which the agreement at issue would be lawful as a matter of antitrust law, regardless of whether the agreement involved IPRs. One example is an agreement to settle a dispute involving blocking

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\textsuperscript{10} See Blair & Cotter, supra note 3, at 513.

\textsuperscript{11} See Thomas F. Cotter, Intellectual Property and the Essential Facilities Doctrine, 44 ANTITRUST BULL. 211, 228 (1999).

\textsuperscript{12} See John R. Allison & Mark A. Lemley, Empirical Evidence on the Validity of Litigated Patents, 26 AIPLA Q.J. 185, 205-07 (1998) (finding that nearly fifty percent of all litigated patents are invalidated).

\textsuperscript{13} See Blair & Cotter, supra note 3, at 514.

\textsuperscript{14} See Hovenkamp et al., supra note 1, at 1723-24.

\textsuperscript{15} See id. at 1724; see also Crane, supra note 7, at 776-79 (stating that courts tend to focus on the parties' intent and ignore the effect of settlements).

\textsuperscript{16} See 12 HOVENKAMP, supra note 2, § 2046, at 262; Hovenkamp et al., supra note 1, at 1721.
patents under which the plaintiff and defendant each agree to grant the other an unrestricted, nonexclusive license to use the other's patent. Absent other, more suspicious terms, this arrangement neither reduces output nor increases price, and therefore does not call for serious antitrust scrutiny.

The second class of cases includes those in which the agreement at issue would be unlawful as a matter of antitrust law, regardless of the presence of valid and infringed IPRs. Here the authors give an example of a hypothetical settlement over a patented windshield wiper blade between Ford and General Motors (GM) that involves an agreement that Ford will license the blade to GM on the condition that Ford will sell pickups only west of the Mississippi, and GM only east. In this instance, even if the patent is both valid and infringed, the territorial market division should be per se unlawful because it bears no plausible relationship to the scope of the patent at issue.

The third class of cases covers the gray area between the above two situations, where antitrust law's disposition of the cases varies. It encompasses agreements that would be

17. "Blocking patents" arise when someone patents an improvement over another patented invention. For example, suppose that Patent 1 (the "dominant" patent) claims an invention comprising limitations A, B, C, and D, and that Patent 2 (usually called the "subservient" patent) claims an invention comprising limitations A, B, C, D, and E. The owner of Patent 1 can prevent others from making, using, or selling any product that contains all of the limitations found in Patent 1; one such product would be the invention claimed in Patent 2, which contains all of those limitations (plus one additional limitation, E). The owner of Patent 1, however, also cannot make, use, or sell the invention claimed in Patent 2, without obtaining permission from the owner of Patent 2. Unless the parties reach agreement with one another, no one will be allowed to make, use, or sell the invention claimed in Patent 2 until Patent 1 expires. See Thomas F. Cotter, Conflicting Interests in Trade Secrets, 48 FLA. L. REV. 591, 591-92 (1996). For further discussion of blocking patents, see Mark A. Lemley, The Economics of Improvement in Intellectual Property Law, 75 TEX. L. REV. 989, 1009-10 (1997); Robert Merges, Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents, 62 TENN. L. REV. 75, 80 (1994).

18. See Hovenkamp et al., supra note 1, at 1725.
19. See id.
20. See id. at 1726.
21. The authors have previously used variations of this example. See, e.g., 12 HOVENKAMP, supra note 2, § 2040(b), at 201-02; 2 HOVENKAMP ET AL., supra note 9, § 33.6(b), at 33-30 to 33-31.
22. See Hovenkamp et al., supra note 1, at 1726.
23. See id.; see also id. at 1730, 1748, 1764-65 (providing other examples of per se unlawful settlements).
unlawful if they did not involve IPRs, but that might be redeemed by the presence of these rights, depending on the facts. The first example the authors give of such a “hard case” is an agreement to settle a blocking patents dispute, under which the parties agree to cross-license one another, but on terms that are more restrictive than under the first, clearly lawful example—e.g., by granting each other exclusive or otherwise more restrictive licenses. This kind of agreement promotes competition if both patents are valid and infringed, because in the absence of an agreement patent law would give each party the right to exclude the other from using the subservient patent at all. Supposing instead that at least one of the patents is invalid or that the subservient patent does not infringe the dominant patent, an agreement that the parties will grant each other exclusive licenses reduces competition, assuming the court would have resolved the validity and infringement issues correctly. Litigation would result in one or the other (or both) patents being relegated to the public domain, free for others to use at will, or at the very least, the holder of the subservient patent would be free to use its invention without permission of the dominant patent owner. Thus, in a case in which a dominant and a subservient patent owner agree to settle their dispute by granting one another exclusive licenses, neither a rule of per se legality nor a rule of per se illegality seems appropriate. A per se illegality rule would be unwise, even though the parties could have chosen a less restrictive alternative than the one they actually chose, because requiring the antitrust tribunal to routinely scrutinize settlement agreements for less restrictive alternatives would be burdensome. In addition, the alternative the parties chose, while less encouraging of competition than other possible choices, is nevertheless within the permissible scope of behavior under patent law, provided that both patents are valid and the dominant patent is infringed. A rule of per se legality

24. See id. at 1726-27.
25. See id.
26. See supra note 17 (defining subservient).
27. See supra note 17 (defining dominant).
28. This assumes that collateral estoppel would apply, which in fact it normally would. See Blonder-Tongue Lab., Inc. v. Univ. of Ill. Found., 402 U.S. 313, 317-28, 338-45 (1971).
29. Indeed, requiring the parties to choose a less restrictive alternative might reduce the returns on research and development and, at the margin, deter some inventive activity. See Carl Shapiro, Antitrust Limits to Patent
would be unwise as well, because in a case in which both are aware that one or both patents is likely invalid due to the existence of, for example, some prior art, or that the subservient patent does not infringe, this rule would give carte blanche to the dominant and subservient patent owners to agree to a naked market division.

This analysis suggests that an antitrust tribunal considering the legality of a settlement falling into the middle ground must conduct some inquiry into the merits of the underlying IP dispute. To this end, Professor Hovenkamp in previous work and Hovenkamp, Janis, and Lemley in their present article propose a three-part test. The court should first determine whether the agreement at issue would violate the antitrust laws if it were not an attempt to settle a dispute involving IPRs. If it would not, the case falls within the first class of cases discussed above and the agreement is per se lawful. If the agreement would otherwise violate antitrust laws, the court must next inquire into whether the parties "did have a bona fide dispute" and whether "the settlement is a reasonable accommodation, and . . . not more anticompetitive than a likely outcome of the litigation." Finally, a court facing uncertainty "must also consider whether the parties might have settled on alternative, less restrictive terms." Thus, while cases falling into the first two categories discussed above can be decided on antitrust grounds alone, with no inquiry into the merits of the underlying IP dispute, cases falling into this third category "must be decided on the basis of IP policy rather than antitrust policy." Referring to the inquiry to be conducted under the three-part test as an application of the rule of reason is, as the authors point out, a misnomer. The ultimate question to be answered under a rule of reason analysis is whether a particular restraint increases or reduces output. In the present context, that question "really reduces to nothing more than the validity of the underlying patent" (or other IP right).

As suggested above, I find nothing faulty in this overall

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30. See Hovenkamp et al., supra note 1, at 1728.
31. See id. at 1727.
32. Id.
33. Id. at 1728.
34. Id. at 1731.
framework, and indeed I have cited with approval Professor Hovenkamp’s earlier version of it. Where more work remains to be done is in refining the application of the three-part test to the middle class of cases involving settlement agreements; as is so often the case, the devil is in the details. As the authors recognize, the dilemma presented by the three-part test is that requiring antitrust tribunals to scrutinize the merits of a settled IP dispute threatens to unravel the substantial private and social benefits to which the settlement gives rise, including the reduction in litigation costs that settlement generally promotes. The authors note that one way to avoid this problem in some cases is to focus on other elements of the antitrust claim. For example, if the parties to the settlement agreement lack market power, or the agreement does not foreclose competition within a properly delineated market, a court may dismiss the antitrust claim on antitrust grounds alone, without any further inquiry into the validity of the IPRs and their infringement. Thus, even within the third class of cases, not every settlement will necessarily result in an inquiry into the underlying merits. Only when the antitrust tribunal cannot resolve the antitrust claim on antitrust grounds alone must it apply the three-part test, considering whether there was “a legitimate dispute about the existence of an IP right and likely infringement of a valid IP right,” and whether the agreement falls “within the range of permissible outcomes of litigation . . . no more anticompetitive than such an outcome would have been.”

Even under this analysis, several important issues remain, including the allocation of the burden of proof with respect to validity and infringement (or invalidity and noninfringement). Hovenkamp, Janis, and Lemley favor allocating the burden to the settling parties/antitrust defendants, because those parties generally will be in a better position to prove that valid IPRs were infringed than will be the antitrust plaintiff to prove that such rights were not infringed. I agree with this conclusion as a general matter, and I have made the same observation with respect to one type of settlement in particular, namely the settlement of patent litigation involving “reverse payments”

35. See Blair & Cotter, supra note 3, at 517-18.
36. See Hovenkamp et al., supra note 1, at 1732.
37. See id. at 1732-33.
38. Id. at 1734.
39. See id. at 1733-34.
from the patent plaintiff to the patent defendant. In previous

40. See Blair & Cotter, supra note 3, at 534-35. Commissioner Leary has also argued against allocating the burden of proving invalidity and noninfringement to antitrust plaintiffs such as the Federal Trade Commission (FTC), on the ground that it lacks the institutional capability to make such determinations. See Thomas B. Leary, Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II, 34 J. HEALTH L. 657, 661-62 (2001). In theory, one could increase the FTC's budget so that it could acquire the necessary expertise, if there were obvious benefits to be gained from placing the burden on the antitrust plaintiff. It is not clear to me what these benefits would be, however, given that the parties to the settlement almost always would be in a better position to prove validity and infringement than would an outsider, even a very knowledgeable one. Moreover, in the short run, before the FTC could acquire the needed expertise, allocating the burden to the antitrust plaintiff might, at the margin, make some settlements effectively unreviewable and hence per se lawful. For the reasons discussed above, I agree with Hovenkamp, Janis, and Lemley that per se legality is uncalled for in cases of this nature.

One argument against requiring the patent plaintiff/antitrust defendant to prove patent validity is that doing so would contradict the statutory presumption of patent validity. See 35 U.S.C. § 282 (2000) ("A patent shall be presumed valid."); In re Schering-Plough Corp., No. 9297, slip op. at 103-05 (Fed. Trade Comm'n June 27, 2002) (initial decision), available at http://www.ftc.gov/os/2002/07/scheringinitialdecisionp2.pdf; Kevin D. McDonald, Patent Settlements and Payments that Flow the "Wrong" Way: The Early History of a Bad Idea, 15 ANTITRUST HEALTH CARE CHRON. 2, 12-13 (2002). There is, to be sure, some tension between the language of § 282 and the procedure proposed above. A court could resolve this tension, however, by concluding that the statutory presumption was intended to apply in patent infringement actions only, and not in other settings; to hold otherwise might undermine the equally important federal policies embedded in the antitrust laws. In addition, or alternatively, a court could incorporate the statutory presumption into the analysis by requiring the patent plaintiff/antitrust defendant to prove that it would have prevailed in the patent infringement action in light of, inter alia, the statutory presumption. See Blair & Cotter, supra note 3, at 533. At first blush, this solution seems problematic, because it might appear that the patent owner could rely upon the presumption alone to meet its burden of proof. In the analogous setting of a motion for a preliminary injunction, however, a patent owner cannot rely upon the presumption alone to establish a likelihood of success on the merits with respect to validity, if the defendant "raises a substantial question concerning validity." Helixf Ltd. v. Blok-Lok, Ltd., 208 F.3d 1339, 1351 (Fed. Cir. 2000); see also New Eng. Braiding Co. v. A.W. Chesterton Co., 970 F.2d 878, 882-83 (Fed. Cir. 1992). Precisely such a challenge frequently will have been raised in Hatch-Waxman cases, which I discuss infra in Part II, because a firm filing an Abbreviated New Drug Application (ANDA) must provide a detailed opinion supporting its claim of invalidity or noninfringement. See Hovenkamp et al., supra note 1, at 1753 (citing 21 U.S.C. § 355(j)(2)(B)(i)-(ii); 21 C.F.R. §§ 314.50(i), 314.94(a)(12) (2002)). Thus, in the antitrust context a court could require the defendants to prove that the patent owner probably would have prevailed in the patent action, in light of the contrary evidence cited by the ANDA filer and, if desired, in light of the statutory presumption of validity. Note that if both parties to the patent action are defendants in the antitrust
work I argued in favor of the "quick-look" approach to this type of agreement, meaning that the antitrust plaintiff would satisfy its burden of production by showing that the settlement involved reverse payments, at which point the burden would then shift to the settling parties/antitrust defendants to demonstrate that the settlement was lawful.\footnote{See Blair \& Cotter, supra note 3, at 534. I now recognize that it may be preferable to avoid the term "quick-look," insofar as the ultimate inquiry will be one of patent validity and infringement, rather than typical antitrust issues. For this reason, in the title of this Commentary I use the term "presumptive illegality" to convey the idea that proof of reverse payments or other facts showing that the settlement falls into the middle category of cases shifts the burden to the antitrust defendants to prove that the settlement satisfies the three-part Hovenkamp, Janis, and Lemley test.}

Further questions remain, and it is in this regard that one can fruitfully elaborate upon the Hovenkamp-Janis-Lemley framework. In particular, courts still need to work out the details of how the antitrust defendants can meet their burden of proving validity and infringement. Must they prove these facts in the same manner and to the same extent as they would have had to prove them in the patent suit, or can the inquiry be truncated in some respects? Part II provides some tentative thoughts on this issue within the context of the reverse payments phenomenon.

II. REVERSE PAYMENTS

As Hovenkamp, Janis, and Lemley note, one type of settlement that recently has become controversial is the settlement—sometimes final, sometimes interim—of a patent infringement action in which the patent plaintiff agrees to pay the defendant in return for the latter's agreement not to make, use, or sell an allegedly infringing product.\footnote{See Hovenkamp et al., supra note 1, at 1749.} What makes these settlements unusual is that the settlement payment goes from plaintiff to defendant rather than, as one would assume is more common, from defendant to plaintiff. There are now a
handful of documented instances in which the parties have agreed to settlements incorporating reverse payments. 43 Most of them have arisen in one rather peculiar setting, namely patent litigation conducted in the shadow of the Hatch-Waxman Act. 44

As the authors explain, Hatch-Waxman was designed in part to speed the entry of generic drugs to the marketplace. 45 The Act’s rather byzantine statutory scheme has created some unintended incentives to engage in anticompetitive behavior. One problem arises in connection with the filing of Abbreviated New Drug Applications (ANDAs) by companies that want to market generic versions of approved drugs. Under Hatch-Waxman, a company filing an ANDA must demonstrate only that its product is bioequivalent to a drug that the Food and Drug Administration (FDA) has already approved for marketing; upon making this showing, the generic


44. As I discuss below, there are some plausible scenarios, not dependent upon the peculiarities of Hatch-Waxman, in which a patent plaintiff might agree to a stipulated injunction in conjunction with a payment to the defendant. See infra text accompanying notes 68-75. There are also a few documented cases involving reverse payments and not arising in connection with Hatch-Waxman. See Robert J. Hoerner, Antitrust Pitfalls in Patent Litigation Settlement Agreements, 8 FED. CIR. B.J. 113, 121-23 (1998).

45. See Hovenkamp et al., supra note 1, at 1751.
manufacturer may rely upon the safety and effectiveness tests that already have been conducted by the pioneer drug manufacturer, and need not duplicate those tests.\textsuperscript{46} The ANDA applicant also must certify that its generic drug will not infringe any patent covering an approved drug listed in the FDA's Orange Book.\textsuperscript{47} In particular, the applicant may certify, inter alia, that the patent allegedly covering the approved drug is either invalid or will not be infringed by the generic.\textsuperscript{48} Upon receipt of notice of the filing of this particular certification (known as a Paragraph IV certification), the pioneer manufacturer has forty-five days to file suit against the ANDA applicant for patent infringement.\textsuperscript{49} If no suit is filed within this time period, the FDA will approve the drug for marketing immediately.\textsuperscript{50} Significantly, any suit filed by the pioneer within the forty-five day period would be premature under normal patent law principles. Until the FDA approves the generic drug for marketing, the generic manufacturer cannot market its allegedly infringing product; thus, at the time the pioneer patent owner files suit pursuant to Hatch-Waxman, the generic manufacturer has not yet made, used, or sold any product covered by the patent. The Patent Act nevertheless defines the filing of an ANDA as an act of technical infringement, thus permitting the pioneer suit to proceed.\textsuperscript{51} If the pioneer does file suit within the forty-five day period, it obtains an automatic stay of FDA approval of the ANDA, until (1) the patent expires, (2) the patent litigation results in a final judicial determination of invalidity or noninfringement, or (3) thirty months have passed, whichever occurs first.\textsuperscript{52} Since most patent suits take more than thirty months to resolve, the pioneer manufacturer effectively obtains a thirty-month stay.

\textsuperscript{47} See 21 U.S.C. § 355(j)(2)(A)(vii); Blair & Cotter, supra note 3, at 505; Hovenkamp et al., supra note 1, at 1753.
\textsuperscript{49} See 21 U.S.C. § 355(j)(5)(B)(iii); Blair & Cotter, supra note 3, at 505; Hovenkamp et al., supra note 1, at 1753.
\textsuperscript{50} See 21 U.S.C. § 355(j)(5)(B)(iii); Hovenkamp et al., supra note 1, at 1753.
\textsuperscript{51} See 35 U.S.C. § 271(e)(2) (2000); Hovenkamp et al., supra note 1, at 1753 n.146.
\textsuperscript{52} See 21 U.S.C. § 355(j)(5)(B)(iii); Blair & Cotter, supra note 3, at 505-06; Hovenkamp et al., supra note 1, at 1753.
unless the case settles or the patent expires first. Moreover, in some instances, pioneer drug manufacturers have been able to obtain multiple stays by listing additional patents in the Orange Book. Recent proposed regulations, if valid and implemented, would curtail that practice.

The reverse payment settlements that have attracted attention in recent months all arose within the ANDA context. In some instances, the pioneer and the generic manufacturer agreed to an interim settlement under which the generic manufacturer agreed not to market its product pending trial and the pioneer agreed to pay the generic manufacturer a sum of money in return. In others, the parties reached a final settlement involving payments from the pioneer to the generic firm. In either form, these agreements raise several antitrust concerns. It seems likely that in most cases the patent at issue confers market power, meaning the ability to raise prices and lower output, because otherwise the strategy of paying the generic manufacturer not to compete makes no sense. Additionally, it is likely that the pioneer stands to lose more from the entry of generic competition than the generic entrant stands to gain. At first blush, therefore, an agreement under which the plaintiff promises to pay the defendant to delay entry into the market might appear to be a blatant division of monopoly rents. This may be justified if the pioneer’s patent is valid and infringed; but, significantly, the incentive to engage in a division of profits is present even if the patent is neither

53. See Blair & Cotter, supra note 3, at 506; Hovenkamp et al., supra note 1, at 1753-54.
54. See FTC STUDY, supra note 43, at iii-v, 39-56; Hovenkamp et al., supra note 1, at 1754; Steve Seidenberg, Rule on Generics Faces Hurdles, NAT’L J., Nov. 11, 2002, at C1.
57. See Terazosin, 164 F. Supp. 2d at 1346; FTC STUDY, supra note 43, at 31-34.
58. See Hovenkamp et al., supra note 1, at 1757-58.
59. Roger Blair and I have discussed the reasons for this at length in a previous article. See Blair & Cotter, supra note 3, at 524-25.
valid nor infringed. Indeed, the incentive is enhanced because, under another provision of Hatch-Waxman, the first ANDA applicant is given a 180-day period of exclusive generic marketing rights; that is, other generic manufacturers will not be approved until 180 days after (1) the first ANDA applicant begins marketing its drug, or (2) a court determines that the pioneer patent is invalid or not infringed, whichever is earlier. Thus, unless and until the first ANDA applicant actually enters the market, or the pioneer patent is judicially determined to be invalid or not infringed, other generic manufacturers will be precluded from entering and competing against the pioneer and the first generic entrant.

The potential anticompetitive nature of settlement agreements between the pioneer and the generic manufacturers, particularly those involving reverse payments, is therefore apparent. As Hovenkamp, Janis, and Lemley note, antitrust law may not be the only tool available to remedy this potential for abuse. Revisions to the Hatch-Waxman Act and the relevant federal regulations could go a long way toward removing some of the statute's perverse incentives. Unless and until such changes are made, however, the Federal Trade Commission and the courts will have to grapple with the legality of these settlements under antitrust law. To date, a few courts and commentators have condemned settlements involving reverse payments between the pioneer and the generic drug manufacturers as per se unlawful. Others,

61. See Hovenkamp et al., supra note 1, at 1754-55.
62. See id. at 1756.
63. See David A. Balto, Pharmaceutical Patent Settlements: The Antitrust Risks, 708 PLI/PAT 89, 109-10 (2002) (discussing proposed revisions to 180-day rule); Hovenkamp et al., supra note 1, at 1756 (citing proposed legislation and regulations); Julia Rosenthal, Note, Hatch-Waxman Use or Abuse? Collusive Settlements Between Brand-Name and Generic Drug Manufacturers, 17 BERKELEY TECH. L.J. 317, 327-30 (2002) (discussing the McCain-Schumer and Leahy bills); see also supra note 54 and accompanying text.
however, including Blair and myself, have argued that the per se treatment of reverse payment settlements is inappropriate, because these agreements also have some potential to enhance rather than impede efficiency.65 Hovenkamp, Janis, and Lemley fall into the latter camp as well, although they would impose some strict requirements upon the patent plaintiff/antitrust defendant who seeks to justify such an agreement.66 In the following paragraphs, I will explain briefly why these agreements can either enhance or retard efficiency. I will then discuss different ways in which the patent plaintiff/antitrust defendant might attempt to satisfy its burden of proving that a reverse payment settlement agreement enhances efficiency. In this regard, I disagree with one aspect of Hovenkamp, Janis, and Lemley’s proposal, namely their suggestion that the amount of the payment must be less than the patent plaintiff’s avoided litigation expenses.67 In my view, this particular restriction is unnecessarily narrow.

A hypothetical case may help to clarify how these reverse settlement agreements can be either pro- or anticompetitive, depending on the underlying facts. The model that follows draws upon models presented in earlier work by Blair and myself and by Daniel Crane.68 Suppose that the defendant began its alleged infringement at time to; that the parties are

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65. See In re Schering-Plough Corp., No. 9297, slip op. at 96-101 (Fed. Trade Comm’n June 27, 2002), available at http://www.ftc.gov/os/2002/07/ scheringinitialdecisionp2.pdf; Blair & Cotter, supra note 3, at 532-38; Yee Wah Chin & Thomas G. Krattenmaker, Antitrust Update, 2 MERGERS & ACQUISITIONS 30, 37-38 (2001); Crane, supra note 7, at 779-96; Richard J. Gilbert & Willard K. Tom, Is Innovation King at the Antitrust Agencies? The Intellectual Property Guidelines Five Years Later, 69 ANTITRUST L.J. 43, 78-79 (2001); Leary, supra note 40, at 659-61; McDonald, supra note 40, at 12-13; Shapiro, supra note 29 (manuscript at 35). Although none of the sources listed in this footnote advocates a rule of per se illegality, some are much more skeptical than others about the pro-competitive benefits of reverse payment settlements.

66. See Hovenkamp et al., supra note 1, at 1759-60.

67. See id. at 1759.

68. See Blair & Cotter, supra note 3, at 524-25; Crane, supra note 7, at 773.
considering settlement at time $t_1$; and that trial is due to take place at time $t_2$. As of $t_1$, the patent owner has incurred lost profits of $30\text{ million}$. The present value of its estimated future lost profits if the infringement does not cease is $100\text{ million}$, consisting of an additional $10\text{ million}$ in lost profits from now until $t_2$ and $90\text{ million}$ thereafter. The present value of the defendant's estimate of its own lost profits if it ceases to market its product at $t_1$ is $50\text{ million}$, consisting of $5\text{ million}$ in lost profits from now until $t_2$ (call this $G_{\lambda,t_2}$) and $45\text{ million}$ thereafter. As of $t_1$, the plaintiff's expected benefit from going to trial can be expressed as

$$E[B]_{\pi,t} = P_{\pi}[\pi + \delta_{\pi}(D_{\pi,t_1} + D_{\pi,t_2})] - C_{\pi,t},$$

where $P_{\pi}$ is the plaintiff's estimate of the probability of success on the merits; $I_{\pi}$ is the plaintiff's estimate of the present value to it of obtaining an injunction at $t_2$; $D_{\pi,t_1}$ is the plaintiff's estimate of its damages at $t_1$; $D_{\pi,t_2}$ is the plaintiff's estimate of the additional damages it will incur from $t_1$ to $t_2$; $\delta_{\pi}$ is the portion of its damages that the plaintiff expects to be able to collect from the defendant, where $0 \leq \delta \leq 1$; and $C_{\pi,t}$ is the plaintiff's estimate of the present value of its future litigation costs. The defendant's expected loss if it goes to trial can be expressed as

$$E[L]_{\lambda,t} = P_{\lambda}[\lambda + \delta_{\lambda}(D_{\lambda,t_1} + D_{\lambda,t_2})] + C_{\lambda,t},$$

where $P_{\lambda}$ is the defendant's estimate of the plaintiff's probability of success on the merits; $I_{\lambda}$ is the defendant's estimate of the present value of its loss if an injunction issues.

69. These values are roughly consistent with the analysis, presented by Blair and myself, in which we assumed that the hypothetical patent owner's profit would fall by $100\text{ million}$ annually following the introduction of a generic drug, and that the generic manufacturer's annual profits would be between 50% and 70% of the patent owner's profit. Blair & Cotter, supra note 3, at 524-25. For the reasoning behind these assumptions, see id. In the context of Hatch-Waxman, once the generic manufacturer enters the market other generic manufacturers may follow after 180 days, see supra text accompanying note 59, which would further deplete the generic manufacturer's profit margin. Following the introduction of the generic, the pioneer patent owner may continue to market its brand-name drug, at a higher price, to those price-insensitive consumers who prefer the brand name. See Blair & Cotter, supra note 3, at 497-99. The pioneer's profits will decrease, because it is selling to a smaller group of consumers, albeit at a higher price, but they will not fall to zero.
at $t_r$; $\delta \Delta (D_{\Delta t} + D_{\Delta t})$ is the defendant's estimate of the amount of damages it will pay if it is found liable; and $C_{\Delta T}$ is the defendant's estimate of the present value of its future litigation costs. For simplicity, assume symmetric information, i.e., $P_\pi = P_\Delta$ and $\delta_\pi D_\pi = \delta_\Delta D_\Delta$; that the defendant will not be judgment-proof, i.e., $\delta = 1$; and that $P = .75$, i.e., the plaintiff has a 75% chance of prevailing at trial. On these facts, the plaintiff's expected benefit from proceeding with litigation is $.75(90 + 30 + 10) - C_\pi, T = $97.5 million - $97.5 million; the defendant's expected loss is $.75(45 + 30 + 10) + C_{\Delta T} = $63.75 million + $63.75 million. A settlement under which the defendant immediately ceases its infringement, and neither party pays any money to the other, brings the plaintiff $100 million in immediate benefits ($I_\pi + D_{\pi t}$) and brings the defendant $50 million in immediate losses ($I_\Delta + G_{\Delta t}$). A rational defendant therefore would be willing to settle the case by agreeing to cease infringement and pay the plaintiff up to $13.75 million + C_{\Delta T}$. A rational plaintiff would be willing to accept the promise to cease infringement and to accept payment of at least -$2.5 million - $2.5 million. In other words, the plaintiff would be willing to pay the defendant as much as $2.5 million + C_{\pi T}$ to settle the case. To put it another way, the range of possible payments stretches from a “reverse payment” of $2.5 million, to a payment from defendant to plaintiff of $13.75 million, aside from litigation costs. Thus, even when the plaintiff's chances of prevailing at trial are quite good, it is conceivable that the parties might agree to a settlement under which the plaintiff would pay the defendant.

Generally, one would expect the parties to settle when the expected benefit of settlement exceeds the expected benefit of litigation. The monetary aspect of the settlement agreement will satisfy the following condition:

$$E[B]_\pi, T - E[B]_\pi, S \leq SP \leq E[L]_{\Delta T} - E[L]_{\Delta S},$$

where $E[B]_\pi, S$ is the expected benefit to the plaintiff of settling; $E[L]_{\Delta S}$ is the expected loss to the defendant of settling; and SP is the settlement payment. Substituting terms shows that

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70. More realistically, one would not expect the defendant to continue marketing during $t_r$ if its expected loss from doing so (here $7.5 million) exceeded its expected gain (here $5 million), although strategic considerations or other factors may weigh in the defendant's calculation.
Now consider the parties' incentives under Hatch-Waxman. Once the plaintiff files suit, it obtains an automatic thirty-month stay, so the defendant may not market any infringing product as of $t_1$. $D_t$ therefore equals 0. $D_2$ and $G_2$ may be greater than or equal to zero, but they will tend toward zero if (1) the plaintiff obtains multiple stays\(^7\) or (2) trial is expected to occur within thirty months of $t_0$. Moreover, $\delta$ may be significantly less than 1, if the generic manufacturer has few assets or sources of income other than the drug at issue.\(^7\) As $\delta$, $D_2$, and $G_2$ approach zero, equation (4) becomes

\[
P(\pi(I_\pi + \delta_\pi(D_{\pi,1} + D_{\pi,2}))) - C_{\pi,T} + (I_\pi + D_{\pi,2}) \leq SP \leq P_\Delta(I_\Delta + \delta_\Delta(D_{\Delta,1} + D_{\Delta,2})) + C_{\Delta,T} - (I_\Delta + G_{\Delta,2}).
\]

Two observations follow from this equation. The first is that the amount the plaintiff will agree to pay ranges from $C_{\pi,T}$ when $P_\pi = 1$ (i.e., the plaintiff is 100% certain of victory at trial)\(^7\) to $C_{\pi,T} + I_\pi$ when $P_\pi = 0$ (i.e., the plaintiff is 100% certain of losing at trial). At any probability in between, the plaintiff will agree to pay the defendant up to $C_{\pi,T}$ plus some portion of $I_\pi$, as set forth in the table below. Significantly, the plaintiff will always be willing to pay the defendant something to settle.\(^7\) Second, when the defendant is 100% certain that its product would infringe ($P_\Delta = 1$), the defendant will be willing to pay $C_{\Delta,T}$ to settle. When the defendant is sure that its product would not infringe ($P_\Delta = 0$), the defendant would be willing to accept $I_\Delta - C_{\Delta,T}$. At some intermediate probability, the defendant would be willing to accept some portion of $I_\Delta$, minus the litigation expenses it will avoid by settling. Table 1 illustrates the range of likely settlement values for different probabilities of success.

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\(^7\) See supra text accompanying notes 54-55.
\(^7\) See Blair & Cotter, supra note 3, at 524-25.
\(^7\) Hovenkamp, Janis, and Lemley note this point as well. See Hovenkamp et al., supra note 1, at 1758 (citing Shapiro, supra note 29 (manuscript at 35)).
\(^7\) See McDonald, supra note 40, at 9 (making this point); see also Shapiro, supra note 29 (manuscript at 19-21).
Table 1: Assume that $P_\pi = P_\Delta = P$; $I_\pi = 90$ million; and $I_\Delta = 45$ million.

<table>
<thead>
<tr>
<th>$P$</th>
<th>Amount plaintiff will pay defendant</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>$90m + C_{\pi,T} \geq SP \geq 45m - C_{\Delta,T}$</td>
</tr>
<tr>
<td>.25</td>
<td>$67.5m + C_{\pi,T} \geq SP \geq 33.75m - C_{\Delta,T}$</td>
</tr>
<tr>
<td>.50</td>
<td>$45m + C_{\pi,T} \geq SP \geq 22.5m - C_{\Delta,T}$</td>
</tr>
<tr>
<td>.75</td>
<td>$22.5m + C_{\pi,T} \geq SP \geq 11.25m - C_{\Delta,T}$</td>
</tr>
<tr>
<td>1</td>
<td>$C_{\pi,T} \geq SP \geq -C_{\Delta,T}$</td>
</tr>
</tbody>
</table>

One can devise further variations on the model. If the defendant is expected to market a product at some point between $t_1$ and $t_2$, payment will be determined as follows:

(6) $P_\pi[I_\pi + \delta_\pi D_{\pi,t_2}] - C_{\pi,T} - (I_\pi + D_{\pi,t_2}) \leq SP \leq P_\Delta[I_\Delta + \delta_\Delta D_{\Delta,t_2}] + C_{\Delta,T} - (I_\Delta + G_{\Delta,t_2})$.

Alternatively, if the parties agree to an interim settlement only, the settlement substitutes for a preliminary injunction, in which case the only costs avoided are the litigation expenses that would have been incurred in the course of obtaining a preliminary injunction (attorney's fees, any nonrefundable expenses relating to the procurement of a bond, and so on) and $D_{t_2}$. Thus,

(7) $P_\pi(\delta_\pi D_{\pi,t_2}) - C_{\pi,PI} - D_{\pi,t_2} \leq SP \leq P_\Delta(\delta_\Delta G_{\Delta,t_2}) + C_{\Delta,PI} - G_{\Delta,t_2}$.

Even under these scenarios, and even with a high probability of success on the merits, the plaintiff may agree to pay the
defendant to settle. Finally, if risk aversion or asymmetric information are added to the mix, reverse payments may occur even when $P_s$ is very high.

The fundamental point is that the plaintiff often will have an incentive to pay the defendant not to enter the market, regardless of whether the former expects to win at trial. This conclusion suggests that reverse payments should not be per se illegal, since they are just as consistent with a high probability of validity and infringement as they are with a low probability. It also suggests that reverse payments should not be per se legal for the same reason. In particular, if the probability of success is below 50%, the settlement should be condemned as an unlawful restraint of trade under the analysis presented in Part I. A settlement involving reverse payments falls within the middle class of cases in which the antitrust tribunal must consider whether the plaintiff was likely to succeed on the merits and whether the settlement is consistent with a likely outcome at trial. A crucial question is whether this inquiry can be answered without having to go through a patent trial-within-a-trial in the antitrust case.

The antitrust tribunal has at least three options. The first is to have a patent trial-within-a-trial, complete with Markman hearings and expert testimony about damages. At the margin, if the probability that a reverse payment settlement would provoke an antitrust suit is one and if the expected cost of defending such a suit is the same as the expected cost of going to trial in the patent case, rational parties would take this into account in structuring the settlement, such that the expected benefit of settlement would not include any savings in litigation costs. In other words, equation (5) would reduce to

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75. In equation (6), for example, if $\delta = .75$, $P = .75$, and the other values are as hypothesized above, then equation (6) reduces to $0.75(90 + 0.75(10)) - C_{\pi_T} - (90 + 10) \leq SP \leq 0.75(45 + 0.75(10)) + C_{\Delta_T} - (45 + 5)$, that is, $-26.875 - C_{\pi_T} \leq SP \leq -10.625 + C_{\Delta_T}$. In equation (7), using the values in the text above and $\delta = .75$, one would expect a payment of between $4.375$ million and $2.1875$ million, abstracting from litigation costs.

76. See Gilbert & Tom, supra note 65, at 77; Shapiro, supra note 29 (manuscript at 25). Even with a very high probability of success, for example, a risk averse plaintiff might be willing to pay something over $C_{\pi_T}$ to avoid a possible erroneous result at trial. Asymmetric or less-than-perfect information also could affect the parties' estimates of the probability of success, the defendant's solvency, or the value of an injunction, and hence the value of settlement.
Under this scenario, if the patent plaintiff and defendant agreed to a settlement under which the defendant promises not to market its allegedly infringing product, plaintiffs might still pay defendants, but the payment range would be narrower, as shown in Table 2.

Table 2: Assume that $P = P_A = P; I = 90$ million; and $I_A = 45$ million.

<table>
<thead>
<tr>
<th>$P$</th>
<th>Amount plaintiff will pay defendant</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>$90m \geq SP \geq 45m$</td>
</tr>
<tr>
<td>.25</td>
<td>$67.5m \geq SP \geq 33.75$</td>
</tr>
<tr>
<td>.50</td>
<td>$45m \geq SP \geq 22.5m$</td>
</tr>
<tr>
<td>.75</td>
<td>$22.5m \geq SP \geq 11.25m$</td>
</tr>
<tr>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

One would expect reverse payment settlements to become much less common under this scenario, for two reasons. As Hovenkamp, Janis, and Lemley note, an alternative to a reverse payment settlement would be for the parties to settle on terms that would permit the defendant to market its product under a license from the plaintiff. Depending upon the amounts involved, this alternative might become more attractive to the parties than a settlement involving reverse payments where the latter does not result in litigation cost savings. Further, the parties must take into account their potential liability should the antitrust tribunal find their settlement to violate the Sherman Act. This risk is clearly higher under the reverse payments scenario than under the licensing scenario. If the parties settle in good faith but are concerned that the antitrust tribunal will not decide the issues of patent scope and validity correctly, they will be even more averse to entering into this type of settlement. If the benefits of
reverse payment settlements are reduced enough, and the costs sufficiently increased, these settlements might disappear altogether.

Hovenkamp, Janis, and Lemley might not view the elimination of reverse payment settlements as a huge loss, and perhaps they are right. It may be that the marginal social benefit of tolerating such settlements is low, given their potential abuse and given the existence of an alternative settlement structure that would be less susceptible to abuse, but the evidence is not so clear. The danger of channeling Hatch-Waxman litigants toward settling on terms that allow the defendant to license the plaintiff's patent and away from settling on terms that involve reverse payments is that doing so threatens to reduce the value of pharmaceutical patents, including valid pharmaceutical patents. Logically, if it were in the plaintiff's interest to license the defendant, the plaintiff would do so voluntarily. The fact that plaintiffs sometimes prefer reverse payments to licenses suggests that reverse payments sometimes promise a higher payoff to the plaintiff than would granting a license. The analysis above further demonstrates that a preference for reverse payments is not necessarily proof of an anticompetitive scheme.

Restricting the parties from settling on terms that involve reverse payments would decrease the value of at least some valid and infringed pharmaceutical patents, although this reduction in value may not matter much.

77. As Hovenkamp, Janis, and Lemley note, if transactions costs are zero the plaintiff would be indifferent between licensing (and extracting all the rent from) the defendant, and manufacturing all of its product itself. See Hovenkamp et al., supra note 1, at 1750. When transaction costs are present and the plaintiff prefers not to license, the most likely reason is that licensing will reduce the plaintiff's expected income. Indeed, there are a number of transaction costs and other related costs that often significantly decrease the patentee's ability to extract rent from the licensee. See Roger D. Blair & Thomas F. Cotter, Strict Liability and Its Alternatives in Patent Law, 17 BERKELEY TECH. L.J. 799, 818 (2002) (discussing the relevant literature); see also McDonald, supra note 40, at 12.

78. Nobody knows whether patents serve their intended purposes of inducing invention, disclosure, and innovation, although there is some evidence that they might, in the pharmaceutical industry in particular. See Wesley M. Cohen et al., Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not) tbl. 1 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000), available at http://www.nber.org/papers/w7552.pdf (suggesting that firms often rank patents below other reasons for engaging in product innovation, but that patents may be relatively more effective at inducing
A reduction in patent value attendant upon forcing some patent owners into their second best settlement option would be small and therefore worth the resulting increase in consumer surplus. 79 Whether patents are good or bad in general, however, is not the issue. For better or worse, patents exist, and they reflect a legislative judgment that their benefits exceed their costs. For antitrust law to undermine the value of valid and infringed patents, which a rule discouraging reverse payments would in some instances do, is troubling. In some respects, such a rule is analogous to a compulsory licensing scheme 80 and yet U.S. law has generally avoided the compulsory licensing of patents, except when, inter alia, compulsory licensing has been deemed necessary to remedy an antitrust violation. 81 Where the violation is hypothetical only, however, a rule that encourages licensing over exclusion is difficult to square with traditional patent and antitrust policy.

79. Ian Ayres has noted that eliminating the last increment of a monopolist's profit increases consumer surplus by a disproportionately large amount. See Ian Ayres, Pushing the Envelope: Antitrust Implications of the Envelope Theorem, 17 Miss. C. L. Rev. 21, 25 (1996); see also Thomas F. Cotter, Intellectual Property and the Essential Facilities Doctrine, 44 Antitrust Bull. 211, 241-43 (1999) (discussing Ayres and related commentary). One problem with applying Ayres's insight to IP matters, however, is that we don't really know how much of a profit reduction will result from a change in any given rule. See Cotter, supra, at 243. Another is that licensing may be a decidedly second-best option under some circumstances, see Blair & Cotter, supra note 77, at 818, and thus the reduction in profit may be substantial, not small, in the present context.

80. It is not exactly a compulsory licensing scheme, to be sure. First, no one is compelling anything. If the parties want to proceed to trial instead of settling, they may do so; or they may settle for reverse payments and take their chances that no antitrust liability will result. Still, a rule that discourages reverse payments necessarily increases the incentive to settle by licensing. Second, unlike a true compulsory licensing system, a rule that discourages reverse payments does not contemplate the existence of some government agency that will determine the license fee. If the parties cannot agree on the amount, no license will issue. Nevertheless, the plaintiff's option of not licensing at all is severely constrained, if licensing is the only realistic option to proceeding to trial.

whatever the merits of that policy may be.\textsuperscript{82} Moreover, taking one settlement option away from the parties may discourage some settlements altogether, and thus reduce the substantial social benefits of private dispute resolution.

A second possibility would be for the antitrust tribunal to conduct a minimal inquiry into patent scope and validity, similar to the inquiry courts conduct to determine if a patent suit is a sham and therefore immune from antitrust scrutiny.\textsuperscript{83} Yee Wah Chin and Thomas G. Krattenmaker have advocated this approach,\textsuperscript{84} and Crane has noted that a “good faith” approach would be consistent with some prior case law.\textsuperscript{85} Crane, however, rejects this standard,\textsuperscript{86} and I too have previously argued against it, on the ground that it would permit too many anticompetitive settlements to escape scrutiny.\textsuperscript{87} A suit with only a 25\% chance of success may not be a sham, but a settlement based upon such a low probability estimate reduces consumer welfare for no apparent offsetting benefit. Such a low standard of scrutiny is therefore not appropriate.

A third possibility would be for some form of truncated inquiry, but not quite as truncated an inquiry as under the option just discussed. One option would be for an abbreviated hearing, analogous to a preliminary injunction hearing, at which the patent plaintiff/antitrust defendant would have to prove to the antitrust tribunal that it was likely to succeed on

\textsuperscript{82} I recognize that there is some tension between my statements cautioning against using antitrust law to undermine patent law, and my suggestion \textit{supra} that courts should require the patent plaintiff/antitrust defendant to prove validity, notwithstanding the presumption of validity that arises under § 282 of the Patent Act. \textit{See supra} note 40. Two points are important, however. First, as noted above, even with the benefit of the presumption, almost half of all litigated patents are invalidated. \textit{See} Allison & Lemley, \textit{supra} note 12, at 205-07. For the antitrust tribunal to ignore the presumption therefore may not affect substantive rights as much as one might expect. Second, I argued \textit{supra} that the allocation of the burden of proof of validity to the antitrust defendants may be necessary to accommodate antitrust policy. \textit{See supra} note 40. It is not as clear to me, however, that patent law must accommodate antitrust policy to the extent of (effectively) requiring parties who wish to settle their dispute to agree to a licensing arrangement.

\textsuperscript{83} \textit{See} Blair & Cotter, \textit{supra} note 3, at 535 n.174.
\textsuperscript{84} Chin \& Krattenmaker, \textit{supra} note 65, at 37-38.
\textsuperscript{85} \textit{See} Crane, \textit{supra} note 7, at 776-79.
\textsuperscript{86} \textit{See id}.
\textsuperscript{87} \textit{See} Blair \& Cotter, \textit{supra} note 3, at 535 n.174.
the merits of its patent claim.\textsuperscript{88} Alternatively, and perhaps more promisingly, one might envision a sliding scale under which the strength of the evidence on validity and infringement would vary depending on the presence or absence of various factors.\textsuperscript{89} For example, Crane suggests that when the patent plaintiff/antitrust defendant has obtained a preliminary injunction from the patent court prior to settlement, the patent court’s finding that there was a likelihood of success on the merits should be entitled to substantial weight.\textsuperscript{90} Similarly, when the amount of the reverse payment is roughly equal to the plaintiff’s saved litigation costs, the analysis above suggests that the patent was likely to have been valid and infringed and therefore only a minimal inquiry into validity and infringement would be necessary. Indeed, Hovenkamp, Janis, and Lemley suggest that reverse payments should be lawful only when, inter alia, the amount of the payment reflects the plaintiff’s litigation cost savings.\textsuperscript{91} Making this a hard-and-fast requirement, however, is unwarranted. Doing so would rule out the availability of reverse payments except in cases in which the patent plaintiff was absolutely certain of prevailing at trial, but absolute certainty is probably rare and reverse payments are to be expected even when the plaintiff’s probability of success is high but not certain. If, as I suggest above, a rule that de facto forbids reverse payments is undesirable, then surely reverse payments should be tolerated when the patent plaintiff has, say, a 75\% chance of succeeding at trial.\textsuperscript{92}

\textsuperscript{88} Crane recommends this procedure, at least for cases in which the patent tribunal did not issue a preliminary injunction. \textit{See} Crane, \textit{supra} note 7, at 785. Crane also suggests the appointment of special masters to assist the antitrust tribunal. \textit{See id.} at 786.

\textsuperscript{89} \textit{See id.} at 779-96 (presenting a similar framework); Gilbert & Tom, \textit{supra} note 65, at 78-79 (listing factors that make reverse payment settlements more or less suspicious).

\textsuperscript{90} \textit{See} Crane, \textit{supra} note 7, at 783-85.

\textsuperscript{91} \textit{See} Hovenkamp et al., \textit{supra} note 1, at 1759.

\textsuperscript{92} One might, however, make a case for requiring evidence that the probability of success was greater than just 50\%. As noted above, the first ANDA filer obtains a 180-day period of exclusivity vis-à-vis other ANDA filers, measured from the date of the earlier of (1) the first ANDA filer’s marketing of a generic product or (2) a judgment of invalidity or noninfringement with respect to the pioneer patent. \textit{See supra} text accompanying note 59. This provision of Hatch-Waxman ups the ante for the pioneer manufacturer, because a favorable judgment or settlement vis-à-vis the first ANDA filer may keep other ANDA filers at bay. This much is obvious, but there is a more subtle point as well. A generic drug may be the bioequivalent of an approved,
A patented drug (and hence potentially FDA-approvable) without necessarily infringing the approved drug patent. See Blair & Cotter, supra note 3, at 510 n.92. (If this were not so, Paragraph IV certifications asserting noninfringement would be a waste of time.) A judgment (or valid stipulated judgment) in favor of the pioneer patent owner effectively means that the first bioequivalent generic drug at issue infringes, but—importantly—it does not necessarily mean that a second bioequivalent drug also would infringe. For example, the patent may cover a method of delivery or a formulation that is identical to the method of delivery or formulation of the first generic, but not the second. See McDonald, supra note 40, at 6. Nevertheless, a judgment (or valid stipulated judgment) in favor of the pioneer patent owner and against the first ANDA filer effectively stays any further ANDAs from issuing, even if the second ANDA filer's product would not infringe. This makes little enough sense when the pioneer patent is clearly valid and infringed by the first generic drug, but the potential competitive harm is magnified when the settlement involves a questionable patent. Of course, if the first ANDA filer remains free to waive its 180-day exclusivity, this problem may be mitigated. I suggest infra that agreements not to waive exclusivity ought to raise a red flag. See infra text accompanying note 97.

Anticipating my response to their article, Hovenkamp, Janis, and Lemley note that there are two components of any rational exit payment: the cost of continued litigation and the value of eliminating competition that the patentee could not expect to exclude after trial. See Hovenkamp et al., supra note 1, at 1758. They then argue that reverse payment settlements should be lawful only to the extent that they reflect the first component and not the second. See id. at 1758-59. In my view, however, the fact that a reverse payment partly reflects the second component does not necessarily mean that the payment should be condemned. Every settlement of every case has a component that reflects uncertainty over the outcome at trial, and in the present context this uncertainty should induce a rational patent plaintiff to pay an amount that is smaller in value than the value it would receive if it prevailed at trial. Of course, the mere fact that a payment is rational does not necessarily mean that it should be lawful. I therefore do not agree with the authors' characterization of my argument as

it will often be rational for pharmaceutical patentees to agree to make exclusion payments to generic competitors, and therefore that the mere existence and size of those payments should not automatically incline courts to find that they are illegal. We do not think it follows that because it is rational for the patentee to agree to an exclusion payment, that payment cannot be anticompetitive. Far from it.

See id. at 1758 (footnote omitted). I also do not think the stated conclusion follows, and I do not believe the text above reflects such a sentiment; reverse payments clearly can be anticompetitive, even if rational. A better statement of my view, as reflected in the text above, is that I do not believe all such payments in amounts exceeding avoided litigation costs should be condemned on antitrust grounds. The fact that some, perhaps most, reverse payment settlements are anticompetitive leads me to conclude that the burden should be on the antitrust defendants to prove validity and infringement. I also think, however, that some settlements in excess of avoided litigation costs are both rational and should be lawful, and thus the proper analysis of reverse payment settlements should involve additional factors. I also recognize, however, that my proposed rule increases administrative costs, and that this is a drawback.
When the amount of the reverse payment is higher than the saved litigation expenses but less than the defendant's potential loss at trial, it is still likely that the patent was valid and infringed, although one can devise cases in which higher payments are consistent with a high probability of success, and low payments are consistent with a low probability of success. This insight led Blair to conclude that whenever the amount of the reverse payment is less than what the defendant could have earned from marketing a noninfringing product, the reverse payment should not be suspect. In light of the possibility of pathological cases, Blair's proposition may be too extreme, but when the antitrust defendants can show that the payment is below the expected amount of the patent defendant's loss if an injunction were to issue, the burden of proving validity and infringement should be somewhat easier to satisfy than at a full-blown infringement trial.

When the amount of the reverse payment is higher yet, the potential for anticompetitive harm is stronger. The above analysis suggests that as the amount approaches the value of an injunction to the patent plaintiff, the patent plaintiff's case

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93. In the hypothetical summarized in Table 1 above, for example, if $P = .75$, $C_{pl} = $5 million, and $I_a = $160 million, the reverse payment could be as high as $45 million, which is equal to $I_a$. Alternatively, suppose that $P = .25$, $I_a = $4 million, and $C_{pl} = $.5 million. On these facts, the defendant would be willing to accept as little as $2.5 million to settle.

94. See Blair & Cotter, supra note 3, at 533-34. As we note, it may not be easy to estimate the defendant's loss if the court were to enter an injunction. See id. at 533 n.171. In the peculiar context of Hatch-Waxman, however, it actually may be easier to estimate the value of an injunction to both the plaintiff and the defendant than in other types of cases. Because pharmaceutical patents often embody discrete products, rather than components of larger products, see Hovenkamp et al., supra note 1, at 1739, and because they sometimes do confer market power, see id. at 1757-58, estimation of both the plaintiff's and the defendant's projected lost profits may be more feasible than in the typical case. In other, more typical, patent cases, estimating the gains and losses attributable to infringement can be a nightmare. See generally Roger D. Blair & Thomas F. Cotter, Rethinking Patent Damages, 10 Tex. Intell. Prop. L.J. 1 (2001). In any event, the suggestions above are simply ways of trying to short-circuit a full-blown inquiry into validity and infringement. If the calculation of the patent defendant's potential loss proves to be more onerous than demonstrating validity and infringement, then the antitrust defendants presumably will opt for the latter.

95. For example, in Abbott Laboratories, the amount of the monthly payment ($4.5 million) was alleged to be at least three times the amount of the defendant's projected losses ($1.5 million). See Compl. ¶¶ 25, 27, In re Abbott Labs., No. C-3945 (Fed. Trade Comm'n May 22, 2000), available at http://www.ftc.gov/os/2000/05/c3945complaint.htm.
becomes weaker. To state an applicable “rule” with more precision, however, may be impossible. As Crane notes, if one could accurately calculate, ex post, the values of $I_1$, $I_2$, and $D$, the amount of the reverse payment would provide sufficient evidence of the parties’ ex ante assessment of the plaintiff’s probable success.\(^{96}\) Unfortunately, the antitrust tribunal may find this task just as difficult as directly assessing the ex post likelihood of validity and infringement. In cases in which the amount of the payment substantially exceeds the parties’ avoided litigation costs, the sensible solution may be to give them a choice of proving either that the payment is consistent with a high probability of success on the merits, in light of the parties’ expected gains and losses, or that the patent is valid and infringed. Presumably the parties will opt for the less costly choice. Both options may deter some reverse payment settlements that are negotiated in good faith and in the shadow of a high probability of success on the merits, but any other procedure may present too high a risk of anticompetitive abuse. Further, the presence of other factors, such as an agreement on the part of the patent defendant not to waive its 180-day exclusivity period in favor of another generic manufacturer or not to market non-infringing substitutes, should be sufficient to trigger more intense scrutiny, or these aspects of the agreement should be condemned on their own terms, even when the amount of the payment is relatively low. These terms otherwise may insulate the patent plaintiff from lawful competition from either the settling defendant or other potential ANDA filers.\(^{97}\)

CONCLUSION

As stated at the outset, I largely agree with Hovenkamp, Janis, and Lemley’s approach to evaluating the anticompetitive potential of IP settlement agreements. With respect to reverse payment settlements, I agree that the antitrust defendant should have the burden of proving validity and infringement with respect to the underlying patent claim, but the antitrust tribunal may be able to short-circuit the inquiry in some cases.

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96. See Crane, supra note 7, at 788-91.
97. See supra note 92; see also Hovenkamp et al., supra note 1, at 1764-65 & n.196 (noting other suspicious aspects of the Cardizem and Terazosin settlements). Other commentators have made similar observations. See Crane, supra note 7, at 794-96; Gilbert & Tom, supra note 65, at 78; McDonald, supra note 40, at 6.
Finally, I disagree with Hovenkamp, Janis, and Lemley's condemnation of all reverse payment settlements in which the amount of the settlement exceeds the plaintiff's avoided litigation costs, even though I think that courts should remain moderately skeptical of such agreements. As a result, my recommended approach is more accommodating of these settlements than the approach suggested by Hovenkamp, Janis, and Lemley, but less accommodating than some other proposed resolutions.