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Antitrust and Patent Law Analysis of Pharmaceutical Reverse Payment Settlements

Herbert Hovenkamp*

So-called “reverse” payments occur when a patentee and infringement defendant settle infringement litigation with an arrangement under which the patentee pays the alleged infringer to stay out of the market for the period of time covered by the settlement.¹ Terms such as “pay for delay” may be more descriptive than the term “reverse payment.”²

Suppose that a widget patentee observes incipient competition from a rival producer and files an infringement action. This lawsuit could be settled by (1) the infringement defendant's purchase of an exclusive or nonexclusive license from the patentee, followed by the defendant's production under the license; or (2) the infringement plaintiff's purchase from the defendant of a promise that the defendant abandon its entry plans. Alternative (1) brings a new rival into the market. It can bring production closer to the competitive level, depending on whether the license is price- or quantity-restricted. It can also encourage further innovation in the market by giving two companies an incentive to improve on the widget. By contrast, alternative (2) keeps the rival out of the market and induces it to drop its suit in exchange for a payment. There are competitive reasons for favoring inclusive rather than exclusive settlements. Outside the context of the Hatch-Waxman Act and pharmaceutical patent disputes, settlements of the second type are very rare.

Settlement agreements that involve a reverse payment plus the infringement defendant's abandonment of the market do not involve a license of any IP right at all. If the dispute is settled by a payment from the defendant to the plaintiff in exchange for the defendant's right to produce under the patent, the settlement is a license. Most IP settlements result in the creation of a license, and the proper scope of such licenses is a legitimate IP concern. By contrast, if the dispute is settled by the infringement plaintiff's payment to the defendant to stay out of the market, there is no license, and thus the policy of the Patent Act encouraging licensing is not invoked. This fact justifies closer scrutiny of exit payments. Potentially anticompetitive IP settlements are entitled to deference when they involve the creation of IP licenses whose scope must be assessed against competitive risks. But when no license is created, no such deference is needed.³

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¹ See 12 Herbert Hovenkamp, *Antitrust Law* ¶2046c (2d ed. 2005).

² See, e.g., C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553 (2006).

³ Cf. *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257 (1979) (agreement requiring royalty payments on patent that never issued could not be patent “misuse,” for one cannot misuse a nonexistent patent; distinguishing *Brulotte v. Thys Co.*, 379 U.S. 29 (1964), which found misuse

For example, we would not permit parties to settle an ordinary breach of contract dispute by an agreement fixing their prices or dividing their markets.⁴ To be sure, this observation does not completely settle the issue. If a patent is valid and infringed, then the infringement defendant can be excluded without the need for the payment, and the settlement merely produces that result.

In a perfectly functioning market with no transaction costs, a monopoly producer would very likely be indifferent as to producing everything itself or simply licensing another to make part of its production. The license fee would be the monopoly markup, output would remain at the monopoly level as it would in any perfect cartel agreement, and the monopolist would earn the same profits, although part of those profits would be paid as license fees rather than as markup on goods that the monopolist produced.

If all parties were completely certain that a patent was valid and infringed, a patentee could either produce all output under the patent itself, or it could license some output to a rival, earning its part of its profits as royalties rather than on sales of the patented product.⁵ However, assuming zero transaction costs, a firm in that position would have no incentive whatsoever to pay another firm to stay out of the market. Given its patent, it could exclude without paying anything at all. This fact may explain why historically nearly all licensing agreements involve licenses given to the infringement defendant contemplating actual production, not exit payments. The exit payment necessarily reduces the patentee's surplus; the license reduces the surplus only if the licensee fee extracts less than the full monopoly rent from the licensee.

Transaction costs change the picture somewhat. First, if winning an infringement suit and obtaining an injunction cost \$1 million, then the patentee might be willing to pay the infringement defendant up to that amount to stay out of the market, because the cost of the settlement would be lower than the cost of an injunction achieving the same result. Of course, the settlement would not resolve questions about the patent's validity or coverage while the court's judgment might, making the settlement less valuable.⁶

when the patent had issued and the contract required royalty payments extending beyond the patent's term; see 10 Antitrust Law ¶1782c5 (3d ed. 2011, forthcoming).

⁴ For example, if *A* was a dominant firm and potential rival *B* owed *A* a large sum of money, the parties would not be permitted to settle their dispute with an agreement that *A* would forgive the debt in exchange for *B*'s promise to stay out of the market. In such a case no IP rights are at issue and the "settlement" is a naked market-division agreement.

⁵ Cf. *Intel Corp. v. ITC*, 946 F.2d 821 (Fed. Cir. 1991), where Intel owned a patent on a processor chip but hired Sanyo as its "foundry," or "subcontractor" to produce patents under its license.

⁶ While a court's judgment of validity and infringement would not bind non-parties, the decision could nevertheless have a significant impact on future entrants into the patentee's market.

Reverse payment settlements are almost entirely a consequence of the Hatch-Waxman Act.⁷ Mainly, the Act is designed to facilitate the entry of generic drugs by providing the first generic drug maker to challenge a pioneer drug patent and enter the market with a 180 day period of exclusivity. This period applies during the pendency of the settlement even if the generic is not producing, creating a situation that only the pioneer continues to produce the drug. Under subsequent statutory amendments the generic loses the 180 day exclusivity period if it does not produce and market its generic within sventy-five days of approval of its abbreviated drug application to the FDA (ANDA) and within thirty months of its initial filing.⁸ However, no other generic is entitled to the 180 day exclusivity period, so that particular incentive to enter the market with a generic equivalent is lost.⁹

At this writing the Circuit Courts of Appeal are in a three way split over the antitrust legality of so-called “reverse payment” settlements. The Sixth Circuit has declared them unlawful per se.¹⁰ The Second Circuit and the Federal Circuit (applying Second Circuit law) conclude that they are legal per se provided that the patent infringement litigation leading up to the settlement was not a “sham” and the settlement does not reach beyond the scope of the patent.¹¹ The

⁷ In particular, 21 U.S.C. §355(j). See also ; and see Pub. L. No. 98-417, 98 Stat. 1585 (codified mainly in 21 U.S.C.). See Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich.L.Rev. 37 (2009) (arguing for presumptive antitrust illegality); Joseph Farrell & Carl Shapiro, *How Strong are Weak Patents?*, 98 Am. Econ. Rev. (2008) (similar); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 NYU L.Rev. 1553 (2006) (similar). Cf. Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 Fla.L.Rev. 747 (2002) (similar); Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 Antitrust Bull. 491 (2002) (similar); David W. Opperbeck, *Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*, 98 Geo.L.J. 1303 (2010) (similar).

⁸ 21 U.S.C. §355(j)(5)(D)(i)(I).

⁹The entire regulatory procedure is succinctly described in C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629 (2009). See also MICHAEL A. CARRIER, *INNOVATION FOR THE 21ST CENTURY: HARNESSING THE POWER OF INTELLECTUAL PROPERTY AND ANTITRUST LAW* 345–71 (2009).

¹⁰ *Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003). See also *Schering Plough Corp.*, No. 9297 (F.T.C. Dec. 18, 2003), rev'd, 402 F.3d 1056 (11th Cir. 2005) (FTC's view that such settlements are presumptively unlawful, reversed by Eleventh Circuit's rule of reason approach).

¹¹ *Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212-213 (2d Cir. 2006); *Arkansas Carpenters' Health and Welfare Fund v Bayer AG*, 604 F.3d 98 (2d Cir. 2010), *pet. for cert. filed*, 79 USLW 3370 (Dec 06, 2010)(NO. 10-762); *Ciprofloxacin Hydrochlilde Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008). *Arkansas Carpenters* rejected an antitrust challenge to a \$400 million settlement paid by pioneer to a generic producer not to market a generic version of ciprofloxacin. See Judge Pooler's lengthy dissent from the denial of rehearing *en banc*. 625 F.3d 779 (2d Cir. 2010) (dissenting from denial of rehearing *en banc*). See also *Androgel Antitrust Litigation*, 2010-1 Trade Cas. ¶76914 (N.D.Ga. Feb. 22, 2010); *K-Dur Antitrust Litig.*, 2010-1 Trade Cas.

Eleventh Circuit would apply a rule of reason.¹² The Federal Trade Commission has consistently opposed these agreements as unlawful under Section 5 of the FTC Act.¹³ The Antitrust Division has recently changed its position and now regards them as presumptively unlawful as well, or at least as subject to a truncated rule of reason inquiry.¹⁴

Even if the pioneer drug maker's patent were absolutely invalid the parties to a Hatch-Waxman infringement suit (the pioneer and the first generic) would have a strong incentive to settle. In general the amount of the settlements exceeds the profit expectations that the generic might reasonably anticipate from its own competitive entry plus the 180 day period of exclusivity. That is to say, the settlement is a windfall to the generic.¹⁵ If the generic enters the market and the generic and pioneer behave competitively, prices will drop much closer to production costs and the generic can anticipate a 180 day period of profits at or perhaps somewhere above the competitive level. After 180 days additional generics can enter to the extent of market demand and prices will likely fall further. By contrast, if the two firms settle, only the pioneer will produce, earning the full monopoly profits that demand for the drug warrants, and the generic will share in these profits. That is to say, the two firms will share the monopoly rather than compete with one another, and the settlement will presumably approximate the returns to a legal two-firm cartel.¹⁶ The size of Hatch-Waxman payments

¶76949, 2009 WL 508869 (D.N.J. March 24, 2010) (reverse payment settlement was neither per se illegal nor subject to rebuttable presumption of illegality requiring a competitive justification for the payment because the settlement did not exceed the exclusionary scope of the patent and the infringement lawsuits that preceded it were not objectively baseless); *King Drug Co. v. Cephalon*, 702 F.Supp.2d 514, (E.D.Pa. 2010) (similar).

¹² See *Schering Plough*, supra, and *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003).

¹³ E.g., *Schering Plough*, supra.

¹⁴ See Brief for the United States, *Arkansas Carpenters*, supra, available at 2009 WL 2429249.

¹⁵ Henry N. Butler and Jeffrey Pau Jarosch, Policy Reversal on Reverse Payments: Why Court Should not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation, 98 Iowa L.Rev. 57 (2010) (noting this issue; observing, however, the the availability of reverse payments may in fact increase the number of generic applications and the overall effect may be greater entry of generic drugs). See also *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (“A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive.”). The Hatch-Waxman Act regards the generics filing of its drug application as an act of infringement. See 35 U.S.C. 271(e)(1)-(2). As a result it is very likely that the generic has not invested substantial resources in production at the time the infringement act is triggered.

¹⁶ See *Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 209, noting that if the patent is found invalid, “the total profits of the patent holder and the generic manufacturer on the drug in the competitive market will be lower than the total profits of the patent holder alone under a patent-conferred monopoly.” Ordinarily the two settling parties maximize profits by dividing the monopoly proceeds without affecting its size.

bears this out, with many of them reaching into the several hundreds of millions of dollars.¹⁷

This “windfall” element to the generic is a significant factor. Under the Hatch-Waxman approach *neither* party to the patent infringement suit has an incentive to see the suit through to completion, and this distinguishes these suits from the ordinary, noncollusive patent infringement action. As a result the degree of deference that the courts ordinarily give to settlement actions is unwarranted. The premise of this deference is that both sides have taken litigation risks into account and the settlement represents a reasonable compromise between a finding of infringement, in which the defendant takes nothing and pays damages and a finding of invalidity and noninfringement, in which the patent loses everything. In the Hatch-Waxman context, by contrast, any significant doubt about the validity of the patent creates a situation in which both parties can profit a great deal by entering into the settlement. Indeed, it is more profitable to the infringement defendant to settle than to win. If the patent has a high likelihood of being sustained and infringement found, then the pioneer can be expected to be willing to pay much less.

In the typical infringement case not involving the Hatch-Waxman Act the parties most frequently settle by an arrangement under which the infringement defendant procures a license and produces under royalty requirements during the pendency of the agreement, which typically cannot extend beyond the expiration of the patent.¹⁸ The Patent Act expressly authorizes production licenses of this sort, quite aside from settlement.¹⁹ However, the Patent Act does not authorize exit payments or other payments by patentees to exclude rivals from its market. Further, in a conventional settlement with a production license a high license fee suggests increasing likelihood that the patent was infringed, while in the Hatch-Waxman context it suggests increased likelihood that the patent was either invalid or not infringed.

A very high percentage of the pharmaceutical patents subjected to Hatch-Waxman litigation are found to be invalid or not infringed when courts do reach the merits of the patent infringement suit itself. This number is as high as 73%

¹⁷E.g., *Arkansas Carpenters*, 625 F.3d 779, 780 (2d Cir. 2010) (Pooler, j., dissenting) (\$400 million settlement). See FEDERAL TRADE COMMISSION, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS: AN FTC STAFF STUDY 4 (2010), available at www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf. (estimating consumer costs at \$3.5 billion annually). See also Hemphill, *Aggregate Approach*, 109 *Columbia L.Rev.* at 646 (finding 143 settlements on 101 brand-name drugs during the period 1984, when Hatch-Waxman was passed, through 2008).

¹⁸*Brulotte v. Thys*, 379 U.S. 29 (1964) (invalidating contract calling for royalties to be paid beyond expiration of the patent); see 10 PHILLIP E. AREEDA & HERBERT HOVENKAMP, *ANTITRUST LAW* ¶1782c (3d ed. 2011, in press). See also Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 *RAND J. Econ.* 391 (2003) (discussing harm caused by settlements that go beyond patent term).

¹⁹See 35 U.S.C. §261; and see 12 *ANTITRUST LAW* ¶2044.

according to one FTC Study.²⁰ This may seem surprising, given that pioneer pharmaceutical patents on drug molecules are typically seen as among the more robust patents that are granted.²¹ However, many and perhaps most of the patents subject to Hatch-Waxman style litigation are not primary molecule patents. Rather they are subsequently issued patents on dosage variations, usage variations, or in some cases changes in the form or manufacturing process of the drug, and many of these patents are of much more dubious quality.²² In particular, given that the primary patent already exists, these variations may not pass patent laws requirements of novelty or nonobvious subject matter.²³

This high risk of invalidity or noninfringement findings suggests two things. First, it explains why the pioneer drug manufacturer might have a strong incentive to settle and share the extended profits with the challenging pioneer

²⁰ See FTC, Generic Drug Entry Prior to Patent Expiration (July 2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>. This figure is somewhat higher than for litigated patents generally, where roughly half of litigated patents are found to be invalid. See John R. Allison & Mark A. Lemley, Empirical Evidence on the Validity of Litigated Patents, 28 Am. Intell.Prop.L.Assn. Q.J. 185 (1998)

²¹ E.g., Dan L. Burk and Mark A. Lemley, The Patent Crisis and How the Courts Can Solve it 32-33 (2009).

²² See Aaron S. Kesselhelm and Jerry Avorn, Using Patent Data to Assess the Value of Pharmaceutical Innovation, 37 J.L.Med. & Ethics 176 (2009) (on “evergreening” of secondary patents); Rebecca S. Eisenberg, The Role of FDA in Innovation Policy, 13 Mich. Telecomm. Tech. L. Rev. 345, 347 (2007); Rebecca S. Eisenberg, The Problem of New Uses, 5 Yale J. Health Pol’y L. & Ethics 717, 727 (2005). Indeed, there is some evidence that Hatch-Waxman exacerbates the evergreening problem by facilitating relatively minor secondary patenting and shielding them from more careful post-issuance scrutiny. See Ron A. Bouchard, et al., Empirical Analysis of Drug Approval-Drug Patenting Linkage for High Value Pharmaceuticals, 8 Nw. J. Tech. & Intell. Prop. 174 (2010); Brook K. Baker, Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage, 34 AM. J.L. & MED. 303, 304-306 (2008); Mark A. Lemley & Kimberly A. Moore, Ending Abuse of Patent Continuations, 84 B.U. L. REV. 63, 81 (2004) (on evergreening of pharmaceutical patents); Lara J. Glasgow, Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?, 41 Idea 227 (2001). See also Hemphill, Aggregate Approach, 109 Columbia L.Rev. at 638-639 (describing successive patenting of Lipitor).

²³ E.g., Sun Pharm. Indus. V. Eli Lilly & Co., 611 F.3d 1381 (Fed. Cir. 2010) (discussing obviousness in the context of “double patenting,” or using minor variations in treatment or dosage to file secondary patents on top of a primary patent); Purdue Pharma Prods. L.P. v. Par Pharm., Inc., 377 F.App’x. 978 (Fed. Cir. 2010) (new way of administering established drug invalid for obviousness); Altana Pharma AG v. Teva Pharmaceuticals USA, Inc., 566 F.3d 999 (Fed. Cir. 2009). See also Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 Tex.L.Rev. 503 (2009) (on pharmaceutical evergreening and problems relating to novelty and nonobviousness); Michael Enzo Furrow, Pharmaceutical Patent Life-Cycle management After KSR v. Teleflex, 63 Food & Drug L.J. 275 (2008) (similar); Rebecca S. Eisenberg, Pharma’s Nonobvious Problem, 12 Lewis & Clark 375 (2008); Christine S. Paine, *Brand Name Drug Manufacturers Risk Antitrust Violations By Slowing Generic Production Through Patent Layering*, 33 SETON HALL L. REV. 479, 497-506 (2003).

rather than risk an invalidity finding. In that sense it “explains” reverse payment settlements. Second, however, assuming that the invalidity or noninfringement findings are correct, it also suggests that most of these settlements come with a very high social cost – namely, continued exclusivity protection that is not justified under the Patent Act. A reverse payment settlement does nothing to bring down the price of a pioneer’s drug during its pendency. The generic is not producing at all. To the extent that any portion of the settlement payment can be regarded as a variable cost it will presumably be passed on to consumers in the form of higher, rather than lower, drug prices. That is, as a monopolist’s costs rise its profit-maximizing price typically rises as well.

Theoretically, a reverse payment settlement that calls for termination and production by the generic prior to the expiration date of the litigated patent will bring competition earlier than continued exclusive production under a valid patent that the generic’s contemplated production would infringe. Issued patents are presumed to be valid,²⁴ although there is no presumption in favor of the patentee on questions of infringement. Further, courts are extremely loathe to inquire into the merits of patent settlements even when they involve agreements that would be regarded as unlawful under the antitrust laws in the absence of a patent.²⁵ Nevertheless, a rule of virtual per se legality for reverse payment settlements seems quite inconsistent with Supreme Court precedent that has not hesitated to examine anticompetitive settlement agreements and occasionally find illegality when the practices condoned by the settlement agreement, such as price-fixing or concerted exclusion, are not authorized by the patent act.²⁶ Reverse payment settlements are in this class of situations.

A rule attaching too much significance to the duration of the settlement agreement and whether it terminates prior to patent expiration is inadvisable in any event. The parties can always negotiate a higher payment over a shorter

²⁴ See 35 U.S.C. §282.

²⁵ See 12 Antitrust Law ¶2046.

²⁶Id.; and see, e.g., *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963) (disapproved settlement agreement involved pooling plus exclusion); *United States v. New Wrinkle, Inc.*, 342 U.S. 371 (1952) (cross-licensing with price restrictions); *Hartford-Empire Co. v. United States*, 323 U.S. 386, clarified, 324 U.S. 570 (1945) (horizontal customer restrictions); *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942) (similar). See also *Asahi Glass Co. v. Pentech Pharmaceuticals, Inc.*, 289 F. Supp. 2d 986, 991-992 (N.D. Ill. 2003) (Posner, J.):

Only if a patent settlement is a device for circumventing antitrust law is it vulnerable to an antitrust suit. Suppose a seller obtains a patent that it knows is almost certainly invalid (that is, almost certain not to survive a judicial challenge), sues its competitors, and settles the suit by licensing them to use its patent in exchange for their agreeing not to sell the patented product for less than the price specified in the license. In such a case, the patent, the suit, and the settlement would be devices—masks—for fixing prices, in violation of antitrust law.

period of time and would do so if they could thereby avoid antitrust liability. By contrast, a settlement that calls for the generic to stay out of the market beyond the expiration of the patent should be regarded as a per se unlawful market division.²⁷

Under the Second Circuit's rule reverse payment settlements are lawful unless the underlying patent litigation is a "sham"²⁸ or the settlement agreement goes "beyond the scope of the claims" contained in the patent.²⁹ In one sense, of course, the settlement does not go beyond the scope of the patent, which claims a right to exclude from the product and uses that it covers. In another sense, however, nothing in the Patent Act justifies the exclusion payment, and in this case the exclusion is a consequence of the payment, not of the patent itself. Indeed, as the payment becomes higher the presumed quality of the patent is less, increasing the inference that the exclusion is caused by the payment rather than the patent itself. Further, a reverse payment is a market division agreement which is per se unlawful under antitrust law. In this case the payment is not "ancillary" to anything, because the settling generic is not producing anything. As noted previously, the Supreme Court has not hesitated to condemn anticompetitive settlements under the antitrust laws when those agreements involved naked restraints on trade that the Patent Act did not authorize.

There may be some nonantitrust approaches to this problem.³⁰ One possible solution is to remove the presumption of patent validity upon the showing of a high exit payment. The Patent Act states that patents are presumed to be valid, which means that the burden of proving invalidity rests on the challenger.³¹ But the statutory language says nothing about what it takes to defeat the presumption. In this case, a high exit payment is evidence that the patentee doubts that the patent will survive a validity test in court. Even with the presumption removed, however, a court must still determine whether the patent was valid and infringed, and thus far they have been largely unwilling to do so.

Indeed, one of the driving forces in the debate over the antitrust standard to be applied is the reluctance of courts to second-guess settlements by questioning the validity of the underlying patent or its infringement.³² Both the

²⁷ See, e.g., *Palmer v. BRG of Georgia*, 498 U.S. 46 (1990). On market division agreements generally, see Ch. 20D.

²⁸ A "sham" lawsuit occurs when the right being asserted is so weak that no reasonable litigant would have brought the action. See 3 Antitrust Law ¶706 (sham infringement actions). On "sham" litigation generally, see 2 Antitrust Law ¶205.

²⁹ See *Arkansas Carpenters*, 604 F.3d at 103 (quoting *Cipro III*, 363 F.Supp.2d at 540-541).

³⁰ The argument in the following paragraphs comes from Christina Bohannon & Herbert Hovenkamp, *Creation Without Restraint: Promoting Liberty and Rivalry in Innovation*, ch. 3 (2011, forthcoming).

³¹ 35 U.S.C. § 282.

³² See 12 Antitrust Law ¶2046; and Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1725 (2003).

rule of virtual per se illegality adopted by the Sixth Circuit³³ and the rule of virtual per se legality adopted by the Second Circuit³⁴ are attempt to resolve the antitrust issue without inquiring into the merits of the infringement suit. A full rule of reason query almost certainly means an inquiry into patent validity and infringement. If the patent is valid and infringed by the generic, then even a very large payment from the pioneer to the generic for the full remaining life of the patent represents a wealth transfer between these parties but causes social economic harm only to the extent that the payment increases the pioneer's costs and thus may increase its drug price as well. Of course, a patentee who knew this in advance would be reluctant to make any more than a nuisance value payment. At the other extreme, a patent that is invalid or not infringed should invite immediate generic entry, and the delay imposed by the reverse payment settlement represents both competitive harm and social cost identical to that which flows from any naked market division agreement. The rules of per se and presumptive illegality rest on the premise that a very high payment itself is a strong indicator that the pioneer believes its patent is weak or proof of infringement unlikely. A property owner ordinarily does not ordinarily need to pay large sums to trespassers to keep them away. At the same time, there is no avoiding the fact that the mere availability of large reverse payment settlements substantially undermines the incentives that the generic has to litigate patent validity and infringement to their conclusion..

One possible avenue is to regard a high exit payment as a signal of invalidity, which can then be used to trigger patent reexamination, a process in which the PTO reconsiders a patent based on prior art that has been newly brought to the PTO's attention.³⁵ The PTO's reexamination is based on the best evidence available at the time of the examination, and the presumption of validity does not apply to the reexamination procedure.³⁶ In a patent infringement suit producing an exit payment the prospective generic entrant will already have filed its declaration and evidence to the effect that the patent is either invalid or will not be infringed by the generic.³⁷ The PTO can rely on this evidence and then make its own decision about the patent's validity.³⁸

The PTO's power in a reexamination proceeding is limited, however. For example, while it has the power to declare that a patent is invalid or to narrow its

³³ *Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

³⁴ *Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212-213 (2d Cir. 2006); *Arkansas Carpenters' Health and Welfare Fund v Bayer AG*, 604 F.3d 98 (2d Cir. 2010), *pet. for cert. filed*, 79 USLW 3370 (Dec 06, 2010)(NO. 10-762).

³⁵ See the PTO'S MANUAL OF PATENTING EXAMINING PROCEDURE (rev. ed. July, 2010), §§ 2200 (ex parte reexamination) and 2600 (optional inter partes reexamination, which permits persons seeking reexamination greater participation in the process), *available at* <http://www.uspto.gov/web/offices/pac/mpep/index.htm>.

³⁶ *In re Swanson*, 540 F.3d 1368, 1377 (Fed. Cir. 2008).

³⁷ See 35 U.S.C. § 355(j)(3)(B)(iv)(II) (2006).

³⁸ This is a variation of a proposal made in Gregory Dolin, *Reverse Settlements as Patent Invalidity Signals*, 24 HARV. J.L. & TECH. (forthcoming 2011).

claims, it cannot decide questions of infringement. Further, its power to revisit validity is largely limited to issues of novelty and nonobviousness, which require a reexamination of prior art. Finally, while reexamination typically involves a much closer look than the original patent granting process, it is undertaken by the same agency and under the same rules. As a result, any biases in the PTO in favor of granting patents or of reading prior art too narrowly, will remain.

Nevertheless, reexamination is hardly a paper tiger. Statistics gathered in 2010 indicate that roughly 25% of patents subjected to ex parte examinations are completely confirmed; 10% are completely cancelled; and about 2/3 see their claims changed. By contrast, in *inter partes* reexamination, a more adversarial process, 60% of the patents were cancelled and 35% saw their claims changed.³⁹ An even higher percentage of patents are cancelled in *inter partes* reexamination than are declared invalid in litigation.

Two things must happen to make the automatic reexamination route work, or at least testable as a mechanism for resolving this problem. First, identification of a large reverse payment settlement could trigger a request by an appropriate federal agency (FTC or FDA) for *inter partes* reexamination. This would not require new legislation. In that proceeding the agency, not the settling generic whose interests are compromised, would be the party opposing the patent. The statute permits “any third party requester” to request an *inter partes* reexamination.⁴⁰ Second, however, in order to be a more complete solution the scope of reexamination must be broadened. The current statute permits reexamination only “on the basis of any prior art,” which largely restricts reexamination to questions of novelty and nonobviousness. “Off the record” defects such as the on sale bar cannot ordinarily be attacked in reexamination. Presumably the great majority of invalid secondary drug patents fail for lack of novelty or obviousness, the two inquiries that reside in prior art, but not all do. Once a patent survives reexamination it is still subject to challenge in litigation but is presumably much stronger than when initially issued, and *inter partes* reexamination is itself an adversarial proceeding.

Not all settlement agreements have been validated. For example, on remand from the *Valley Drug* decision the district court granted the plaintiff's motion for summary judgment, and once again found the defendants' exit payment settlement per se unlawful.⁴¹ The court applied a three-part test “to

³⁹ See Alan W. Kowalchuk and Joshua P. Graham, *Patent Reexamination*, 3 LANDSLIDE 47 (Sep./Oct. 2010).

⁴⁰ 35 U.S.C. §311.

⁴¹ *Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005), on remand from *Valley Drug Co., Inc. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003). See 12 Antitrust Law ¶2046c2. The summary judgment grant by the district court settled the issue of illegality of the settlement agreement but left for trial questions about the plaintiffs' injury and damages. See also *K-Dur Antitrust Litig.*, 2009 WL 508869 (D.N.J. Feb. 6, 2009), report and recommendation adopted, 2010 WL 1172995 (D.N.J. 2010) (reverse payment settlement agreement with generic rivals did not restrain trade because (a) it did not exceed scope

of patent given that patentee had right to exclude rivals in any event; and (b) the patent infringement suit leading up to settlement was not shown to be a sham; refusing to apply approach suggested by Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes* ("Hovenkamp"), 87 Minn. L. Rev. 1719, 1753 (2003); *Andrx Pharmaceutical, Inc. v. Elan Corp., PLC*, 421 F.3d 1227 (11th Cir. 2005) (allegations that pioneer and first generic entered an agreement under which first generic would never produce, thus excluding other generic firms from market indefinitely, stated cause of action under both §1 and §2 of the Sherman Act: "Andrx did sufficiently state a claim under both §1 and §2 of the Sherman Anti-Trust Act that Elan's settlement agreement with SkyePharma, coupled with SkyePharma's putative agreement not to market, violated antitrust law.").

See also *Merck & Co., Inc. v. Apotex, Inc.*, 488 F. Supp. 2d 418 (D. Del. 2007), vacated as moot, 287 Fed. Appx. 884 (Fed. Cir. 2008), holding that Merck's giving and Apotex's acceptance of a covenant not to sue settling patent infringement litigation denied the court jurisdiction over the claim and was thus not a triggering event setting the clock running so that Apotex could enter the market. The court observed:

Notwithstanding the body of law that mandates dismissal, the court is sensitive to Apotex's argument that Merck is manipulating the court's jurisdiction. Indeed, the court must guard its jurisdiction jealously. Apotex highlights an interesting yet troublesome practice that has emerged from the interplay of the Hatch-Waxman regulatory scheme, covenants not to sue, subject-matter jurisdiction, and the typical time cycle of a patent litigation. This lawsuit exposes the ability of pioneer drug companies to potentially hold generics at bay by suing them, as they are authorized to do when a paragraph IV certification is made in an ANDA, and then granting a covenant not to sue, which divests the court of subject-matter jurisdiction. In this way, district courts can be viewed as unwitting agents in a pioneer drug company's ability to defer competition for as long as possible. As unfortunate as it may be for Apotex, this is the framework that the Hatch-Waxman Act created. The legislative history suggests that, in fact, Congress contemplated the use of covenants not to sue as a means of resolving any controversy created by the filing of an ANDA:

The provision [a "civil action to obtain patent certainty"]...is intended to clarify that Federal district courts are to entertain such suits for declaratory judgments so long as there is a "case or controversy" under Article III of the Constitution. We fully expect that, in almost all situations where a generic applicant has challenged a patent [by filing an ANDA with a paragraph IV certification] and not been sued for patent infringement, a claim by the generic applicant seeking declaratory judgment on the patent will give rise to a justiciable "case or controversy" under the Constitution. We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug

ensure (1) that the parties did have a bona fide dispute, (2) that the settlement is a reasonable accommodation, and (3) that the settlement is not more anticompetitive than a likely outcome of the litigation.⁴² The court then found that there was a substantial question as to the patent's validity.⁴³ In particular, there was evidence that enforcement of the patent was precluded by the "on-sale bar."⁴⁴ The court ultimately concluded after a lengthy analysis of the on-sale bar issue that the patent would very likely have been found invalid.⁴⁵ Further, the settlement in this case was not one that terminated the litigation; rather, it simply resolved a preliminary injunction issue but kept the underlying litigation as to validity alive—howbeit, giving the parties a strong incentive not to pursue it to its conclusion⁴⁶:

Here, the Agreement did not revolve or even simplify Abbott's patent infringement action against Geneva...; to the contrary, the Agreement tended to prolong that dispute to Abbott's advantage, delaying generic entry for a longer period of time than the patent or any reasonable interpretation of the patent's protections would have provided.⁴⁷

In addition,

the remaining provisions of the Agreement, rather than being catalysts for competition and resolution of litigation, are comprehensive restraints on Geneva's market entry plans

does not infringe.

149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of Senate HELP committee).

Id. at 424-425.

And see *Ranbaxy Laboratories Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006) (striking down FDA regulation making manufacturer of generic drug ineligible for 180 days of market exclusivity if the holder of the new drug application seeks to delist the patent, rather than to litigate validity or infringement).

⁴² Id. at 1295, citing Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, Anticompetitive Settlement of Intellectual Property Disputes, 87 Minn. L. Rev. 1719, 1727 (2003).

⁴³ See id. at 1298 ("...any construction of the patent's exclusionary scope" "...that fails to take into account the chances of the patent being held invalid would essentially afford pioneer drug manufacturers an unbridled power to exclude others without regard to the strength of their patent rights").

⁴⁴ 35 U.S.C. §102b, which can operate so as to preclude patent protection if the invention in the completed form as patented was sold more than one year prior to the filing of the patent application.

⁴⁵ *Terazosin Hydrochloride*, 352 F. Supp. 2d at 1304-1305.

⁴⁶ Id. at 1309 ("where an agreement involves an interim rather than a final settlement, it is far more difficult for the litigants to claim that the agreement was ancillary to an efficient disposition of the litigation"), citing *Schering Plough Corp.*, 2003 WL 22989651 (F.T.C. Dec. 8, 2003).

⁴⁷ *Terazosin Hydrochloride*, 352 F. Supp. 2d at 1309.

that by their very terms far exceed the legal scope of the patent's provisions.⁴⁸

The court then found that these factors were sufficient to warrant application of the per se rule. The court found that the agreement, in which the generic firm accepted large payments (\$4.5 million monthly) for its promise not to compete with the pioneer firm's product, was a naked restraint. "Further, because of the regulatory framework under Hatch-Waxman, the Agreement had the additional effect of delaying the entry of other generic competitors."⁴⁹

As noted above, the Eleventh Circuit vacated the FTC's *Schering-Plough* decision, which had condemned a reverse payment settlement under the FTC Act.⁵⁰ The complex facts can be simplified to these basic ones.⁵¹ Schering produced a potassium supplement called "K-Dur 20," whose principal ingredient was potassium chloride, an unpatentable common substance. The patent at issue covered a material coating that covered the potassium chloride and gave it time-release properties.⁵² Two rivals, Upsher and ESI, both sold formulations of time-release potassium chloride, which they claimed used a different process not covered by the Schering patent. Schering disagreed and sued the two firms for patent infringement. These suits were settled under an agreement requiring Schering to pay Upsher \$60 million and ESI \$15 million for agreements that the

⁴⁸ Id.

⁴⁹ Id. at 1314. The court also noted that the challenged agreement barred Geneva, the generic, "from marketing any terazosin hydrochloride product, including those that were not at issue in the patent case."

⁵⁰ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 548 U.S. 919 (2006). See also *Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 534 (E.D.N.Y. 2005), aff'd, 544 F.3d 1323 (Fed. Cir. 2005), cert. denied, 129 S. Ct. 2828 (2009) (exit payment of \$398 million to generic to stay out of market not an unreasonable restraint because its size suggested that patentee believed that risk that its patent would be found invalid was relatively low:

However, although direct plaintiffs contend that the amount of the exclusion payment in this case—\$398 million—corresponds to a perceived chance of losing of about 50 percent, in absolute numbers Bayer's perceived chance of losing would appear to be much lower. How direct plaintiffs calculated this number is difficult to fathom, especially since they cite Professor Hovenkamp's explanation of expected gains and losses in analyzing the anti-competitive effects of exclusion payments, who states: "[I]f the patentee has a 25% chance of losing, it is willing to pay up to 25% of the value of its monopoly to exclude its competitors without a trial." Herbert Hovenkamp, [Mark D. Janis & Mark A. Lemley,] *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1759 (2003). Applying this model to Bayer's situation—plaintiffs submit that Bayer stood to lose more than \$1.5 billion in profits if the '444 Patent was invalidated—reveals that Bayer's payment of \$398 million translates to a perceived chance of losing of 26.5 percent. Of course, Bayer's payment to Barr was likely also constrained by the maximum amount Bayer expected Barr to make if it won the lawsuit, but applying a straight "expectation" economic analysis to these facts would indicate that Bayer was relatively confident of its chances of winning at trial.

⁵¹ See *Schering-Plough*, 402 F.3d at 1058-1062; and see the FTC's decision, *Schering-Plough Corp.*, 2003 WL 22989651 (F.T.C., Dec. 8, 2003).

⁵² *Schering-Plough*, 402 F.3d at 1058.

latter two firms would stay out of the K-Dur 20 market. However, Schering also obtained a license to market a different drug, Niacor, which was under development at Upsher. That right was subsequently determined to have little value.

In speaking of the proper mode of antitrust analysis for these agreements the Eleventh Circuit stated:

We think that neither the rule of reason nor the *per se* analysis is appropriate in this context. We are bound by our decision in *Valley Drug*⁵³ where we held both approaches to be ill-suited for an antitrust analysis of patent cases because they seek to determine whether the challenged conduct had an anticompetitive effect on the market. By their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present. What is required here is an analysis of the extent to which antitrust liability might undermine the encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability for such exclusionary effects. *Id.* Therefore, in line with *Valley Drug*, we think the proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects.⁵⁴

As the court elaborated:

Although we acknowledged in *Valley Drug* that an agreement to allocate markets is clearly anticompetitive, resulting in reduced competition, increased prices, and a diminished output, we nonetheless reversed for a rather simple reason: one of the parties owned a patent. We

⁵³ Citing *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1311 n.27 (11th Cir. 2003), cert. denied, 543 U.S. 939 (2004).

On remand the district court in *Valley Drug* had once again applied the *per se* rule. See *Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005). The Eleventh Circuit evidently approved in its *Schering-Plough* decision:

We note that the case at bar is wholly different from *Valley Drug*. The critical difference is that the agreements at issue in *Valley Drug* did not involve final settlements of patent litigation, and, moreover, the *Valley Drug* agreements did not permit the generic company to market its product before patent expiration. On remand, the district court emphasized that the “[a]greement did not resolve or even simplify Abbott’s patent infringement action...to the contrary, the Agreement tended to prolong that dispute to Abbott’s advantage, delaying generic entry for a longer period of time than the patent or any reasonable interpretation of the patent’s protections would have provided. Given these material distinctions, the same analysis cannot apply.”

⁵⁴ *Schering-Plough*, 402 F.3d at 1065-1066 n.14.

recognized the effect of agreements that employ extortion-type tactics to keep competitors from entering the market. In the context of patent litigation, however, the anticompetitive effect may be no more broad than the patent's own exclusionary power. To expose those agreements to antitrust liability would obviously chill such settlements.⁵⁵

The court then began its analysis of the settlement agreement at issue with the observation that every patent is presumed valid.⁵⁶ The Patent Act also permits patents to be both assigned⁵⁷ and licensed.⁵⁸ The court then observed:

Although the FTC alleges that Schering's settlement agreements are veiled attempts to disguise a *quid pro quo* arrangement aimed at preserving Schering's monopoly in the potassium chloride supplement market, there has been no allegation that the '743 patent itself is invalid or that the resulting infringement suits against Upsher and ESI were "shams." Additionally, without any evidence to the contrary, there is a presumption that the '743 patent is a valid one, which gives Schering the ability to exclude those who infringe on its product. Therefore, the proper analysis now turns to whether there is substantial evidence to support the Commission's conclusion that the challenged agreements restrict competition beyond the exclusionary effects of the '743 patent.⁵⁹

Although it is true that a patent is presumed to be valid, the issue in the underlying infringement controversy was not whether the patent for K-Dur 20 was valid, but whether the competing products produced by Upsher and ESI infringed that patent. As a general matter there is no presumption that a rival technology infringes a valid patent. Rather, the patentee has the burden of establishing infringement.⁶⁰

By the same token, in and of themselves exit payment settlements are typically not licenses. A common traditional method of settling patent litigation is for the alleged infringer to purchase a license from the patentee, and of course such a settlement includes the license. In a reverse payment case, by contrast, the patentee is simply paying the alleged infringer to stay out of the market, and not to pursue the question of infringement further through litigation. As a result, the settlement does not include a license at all, but merely a naked payment to another to stay out of the payor's market.

The panel rejected the FTC's conclusion that the collateral license for Niacor

⁵⁵ Id. at 1064.

⁵⁶ Id. at 1066, citing 35 U.S.C. §282, and numerous decisions.

⁵⁷ *Schering-Plough*, 402 F.3d at 1066, citing 35 U.S.C. §261.

⁵⁸ *Schering-Plough*, 402 F.3d at 1067, citing several decisions.

⁵⁹ Id. at 1068.

⁶⁰ See, e.g., *Kegel Co., Inc. v. AMF Bowling, Inc.*, 127 F.3d 1420, 1425 (Fed. Cir. 1997).

was in fact a subterfuge, citing evidence in the record that this license was in fact believed to be valuable at the time. In so doing the court accepted the interpretation of the evidence given by the administrative law judge rather than the contrary interpretation subsequently given by the Commission, which reversed the ALJ's decision.⁶¹

To be sure, exposing settlement agreements to antitrust scrutiny chills them, but that does not mean that every settlement is immune from such scrutiny. In this case, a rule permitting scrutiny of reverse payments would do no more than limit agreements calling for such payments. But such payments are of little or no social utility unless they are intended to offset the nuisance costs of a lawsuit.

Further, what the court did not notice is that *all* property rights are presumed valid in the sense that their ownership is not typically questioned in an antitrust case. Property rights can usually be assigned and licensed; however, this does not prevent antitrust tribunals from assessing market divisions or other cartel agreements that cover those rights. Patent rights are property rights and are treated as such except when the Patent Act or special circumstances making patent rights distinctive so warrant. For example, for the owner of a building to license a rival to share a portion of it would almost certainly not be an antitrust violation; however, for the owner to pay a competitor not to build a competing facility would very likely be unlawful *per se*. In sum, IP rights, like all property rights, come with the rights that they have, but these do not include rights to violate the antitrust laws unless a more particularized warrant can be found in the IP statutes or sound policy analysis.

The court's emphasis on the presumption of validity seems to ignore the real anticompetitive threat of many such disputes, including this one, where the question is not whether the patent is valid, but rather whether the infringement defendant's product infringes the patent. While there is a presumption of validity, infringement must be proven, and reverse settlement payments can provide a ready vehicle for permitting a patentee and the maker of a (noninfringing) competing product to cartelize the market. In the case of no infringement the agreement more closely resembles the naked market division agreement among owners of competing buildings, rather than the division of a jointly owned one.

In *Tamoxifen* a pioneer drug manufacturer sued Barr for patent infringement.⁶² After the district court held the patent invalid the parties settled with a scheme under which Barr received a large payment and also a license to produce an authorized generic, provided that the lower court vacated judgment of invalidity, which it did. Subsequent challengers were not able to establish

⁶¹ Assuming that the record contained evidence that a "reasonable mind might accept as adequate to support [the Commission's] conclusion," the court was obliged to accept the interpretation of the Commission rather than the administrative law judge. See *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 454 (1986).

⁶² *Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006), cert. denied, 551 U.S. 1144 (2007). For another critique, see C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553 (2006).

invalidity. The Second Circuit rejected an antitrust challenge, noting its longstanding encouragement of settlements, and refused to upset the traditional presumption of patent validity.⁶³ The Second Circuit majority concluded that the underlying infringement lawsuit was not a sham, and this was sufficient for it to refuse to disapprove the settlement. Indeed, the majority believed that a rule of per se legality was essential “even if it leads in some cases to the survival of monopolies created by what would otherwise be fatally weak patents.”⁶⁴

A dissenter complained:

Holding that a Hatch-Waxman settlement agreement cannot violate antitrust laws unless the underlying litigation was a sham also ill serves the public interest in having the validity of patents litigated.⁶⁵ This interest exists because “[i]t is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.” Litigating the validity of drug company patents is critically important to the general well being in light of the recent trend toward capping the maximum amounts insurers and public benefit plans will spend on medications.

A Hatch-Waxman settlement, by definition, protects the parties' interests as they see them. Whether it also promotes the public's interest depends on the facts. If the validity of the patent is clear, and the generic company receives a license to market the patent holder's product, competition is increased. However, if, as in this case, the patent has already been shown to be vulnerable to attack and the generic manufacturer is paid to keep its generic product off the market, it is hard to see how the public benefits.

The Hatch-Waxman Act provides an incentive for the second kind of agreement that other patent laws do not provide. Patent litigation other than Hatch-Waxman patent litigation generally proceeds along familiar lines. A patent holder sues an alleged infringer, and the infringer either chooses to go to trial to vindicate its view that the patent is invalid or pays the patent holder money as compensation for damages the patent holder has suffered or as the price of a license. In this context, one can perhaps assume that the parties' relative views on the strength of a patent will result in a pro-competitive or neutral result. If the patent holder believes its patent is strong, it will proceed to trial, knowing

⁶³ *Tamoxifen*, 466 F.3d at 202.

⁶⁴ *Id.* at 212.

⁶⁵ Citing *United States v. Glaxo Group Ltd.*, 410 U.S. 52, 57 (1973).

that it can collect damages at the end. The generic manufacturer, if it believes the patent holder's patent is weak, may be willing to risk damages and market its product during the litigation, thereby promoting competition. And if the claims are in relative equipoise, a licensing arrangement may well result.

In contrast, a generic competitor subject to Hatch-Waxman cannot enter the market for the first thirty months after litigation is commenced against it. See 21 U.S.C. §355(j)(5)(B)(iii). In addition, whether its attack against the patent is strong or weak, the benefit it will obtain by successfully litigating to the finish is not great. At best, it will obtain 180 days in which it will be the exclusive generic on the market. See 21 U.S.C. §355(j)(5)(B)(iv). On the other hand, the benefits to the public from the completion of litigation can be enormous if the generic challenger prevails as it did, at least initially, here. Once the 180-day exclusivity period is over, any generic that wishes to market a generic product and that can establish its product is bioequivalent to the patented product can enter the market, thus providing increased competition.

Moreover, the thirty-month stay provides an incentive to the patent holder to pay its generic competitor more than the generic company could have realized from winning the lawsuit. This is so because once the settlement is reached and the litigation dismissed, another generic manufacturer will have to wait at least thirty months after litigation is commenced against it to begin production. Thus, the patent holder will be protected against all generic competition for thirty months after the first lawsuit is terminated. This problem is aggravated when the agreement between the putative competitors provides that the generic company can deploy its exclusivity period after sitting on it until another ANDA applicant attempts to enter the market. These anti-competitive effects—and others not present in this case—have caused antitrust scholars to propose various analytical frameworks for determining whether an antitrust violation has occurred when a patent holder makes a reverse payment to settle patent litigation. The analytical frameworks proposed vary both as to burden of proof and as to the evidence necessary to find a reverse payment illegal.⁶⁶

In the Federal Circuit's decision in *Ciprofloxacin (Cipro)*, Barr filed an ANDA for a generic version of Cipro before the pioneer's patent on the drug and its method of administration had expired, claiming that the pioneer's patent was

⁶⁶ *Tamoxifen*, 466 F.3d at 225-227, citing Herbert Hovenkamp, Mark Janis, and Mark A. Lemley, Anticompetitive Settlement of Intellectual Property Disputes, 87 Minn. L. Rev. 1719, 1759 (2004); Daniel A. Crane, Ease Over Accuracy in Assessing Patent Settlements, 88 Minn. L. Rev. 698, 709 (2004); Thomas F. Cotter, Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis and Lemley, 87 Minn. L. Rev. 1789, 1795-1797, 1802 (2003).

invalid for obviousness.⁶⁷ The parties then settled a patent infringement suit, providing that Barr would not market Cipro under its ANDA until after the patent in question had expired. In exchange Barr received a payment of \$49.1 million initially, plus subsequent payments totaling \$398.1 million. Thereupon followed litigation against other alleged infringers suggesting that the patent was valid, or at least colorably valid. The Federal Circuit concluded that an antitrust market division claim should be tried under the full rule of reason. It rejected the Solicitor General's view that "an appropriate antitrust analysis 'should take into account the relative likelihood of success of the parties' claims, viewed ex ante.'"⁶⁸ The Solicitor General accepted in principle the view that the larger the payment, the more suspicious the patent, thus warranting at least some investigation into the patent's validity or the question of infringement.⁶⁹ The Federal Circuit rejected such an approach:

We disagree that analysis of patent validity is appropriate in the absence of fraud or sham litigation. Pursuant to statute, a patent is presumed to be valid, 35 U.S.C. §282, and patent law bestows the patent holder with "the right to exclude others from profiting by the patented invention." *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). A settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled—a monopoly over the manufacture and distribution of the patented invention. ...Thus, the district court correctly concluded that there is no legal basis for restricting the right of a patentee to choose its preferred means of enforcement and no support for the notion that the Hatch-Waxman Act was intended to thwart settlements....As Judge Posner remarked, if "there is nothing suspicious about the circumstances of a patent settlement, then to prevent a cloud from being cast over the settlement process a third party should not be permitted to haul the parties to the settlement over the hot coals of antitrust litigation."⁷⁰

The court then held that the exclusion license survived rule of reason scrutiny.

⁶⁷ *Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), cert. denied sub nom. *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, 129 S. Ct. 2828 (2009).

⁶⁸ *Id.* at 1337, quoting the Solicitor General's brief in a Second Circuit decision on which certiorari had been denied. See *Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006), cert. denied sub nom. *Joblove v. Barr Labs, Inc.*, 551 U.S. 1144 (2007). In that decision the SG had argued that the petition should be denied, stating that "[a]lthough the petition presents an important and difficult question, and the court of appeals adopted an incorrect standard, this case does not appear to be a good vehicle for resolving the question presented." SG's brief, available at 2007 WL 1511527.

⁶⁹ On this point, see 12 ANTITRUST LAW ¶2046c.

⁷⁰ *Cipro*, 544 F.3d at 1337, quoting *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 992 (N.D. Ill. 2003) (other citations omitted).

Although Bayer, the patentee, did have market power in the relevant market there was no evidence that the agreement restricted the challenges of others to the patent or otherwise restrained competition outside of the patent's ordinary "exclusionary zone."⁷¹ The essence of the agreement in this case was to keep someone other than the patentee from practicing the patent until after its expiration, which was precisely what the patent granted. The court added in a footnote:

Indeed, a sizable exclusion payment from the patent holder to the generic manufacturer is not unexpected under the Hatch-Waxman Act, where the relative risks of litigation are redistributed.⁷²

⁷¹ *Cipro*, 544 F.3d at 1340.

⁷² *Id.* at 1333 n.11, citing *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056, 1074 (11th Cir. 2005), cert. denied, 548 U.S. 919 (2006). See Jessie Cheng, note, An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry, 108 Colum. L. Rev. 1471 (2008); Thomas Chen, Authorized Generics: A Prescription for Hatch-Waxman Reform, 93 Va. L. Rev. 459 (2007); Stacey L. Dogan & Mark A. Lemley, Antitrust Law and Regulatory Gaming, 87 Tex. L. Rev. 685 (2009).