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15.3a1. Entry-restrictive Agreements; Exclusion or “Reverse” Payments

Insofar as antitrust is concerned, among the most problematic settlement agreements are those in which the infringement plaintiff pays the infringement defendant for the latter's abandonment of the market (what we call in this book an “exclusion payment”).⁷⁸ To illustrate, 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 of an agreement from the defendant that it abandon its entry plans. Alternative (1) brings a new rival into the market. It can facilitate competitive production, 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. Thus, there are competitive reasons to favor inclusive rather than exclusive settlements.

In a perfectly functioning market without transaction costs, a monopoly producer would be indifferent between producing everything itself and 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 them would be paid as license fees rather than as markup on goods that it produced.

If all parties were completely certain that a patent was valid and infringed, a patentee would have precisely the same set of incentives. It would either produce all output under the patent itself, or else it would license some output to a rival, earning the monopoly profits as royalties.⁷⁹ Assuming zero

⁷⁸See, e.g., *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 350 F.3d 1181 (11th Cir. 2003). When Zenith and Geneva each began programs to produce a generic equivalent of a pharmaceutical patented by Abbott, Abbott claimed infringement. *Id.* at 1344. It settled both suits, paying Zenith \$3 million and Geneva \$4.5 million each month for their promise to stay out of the market. *Id.* at 1346. The district court's finding that this payment was illegal per se was reversed by the Eleventh Circuit. Compare *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) (finding per se illegality on facts similar to Valley Drug). We intend the term “exclusion payment” to include situations in which the defendant, often a generic pharmaceutical company, never has an opportunity to enter the market, and is paid not to enter, as well as situations in which the defendant is paid to exit a market in which it already competes.

⁷⁹Cf. *Intel Corp. v. United States Intl. Trade Commn.*, 946 F.2d 821, 826 (Fed. Cir. 1991) (involving Intel, which owned a patent on a processor chip but hired Sanyo as its “foundry,” or “subcontractor,” to produce chips under its license).

Uncertainty about the outcome of an infringement suit might also incline the patentee to settle, either by accepting a royalty in exchange for a license or else by making a payment in exchange for the infringement defendant's exit. Under perfect information, the differences between the two types of agreements tend to dissolve. For example suppose that a patent is worth \$1 million per year as long as it excludes everyone, and there is a 60 percent chance that the infringement claim will prevail. In that case that patentee would be willing to pay some amount up to the present value of \$400,000 per year to obtain

transaction costs, however, a firm in that position would have no incentive whatsoever to pay another firm to stay out of the market. It could exclude without paying anything at all. In fact, a large exclusion payment to an infringement defendant might simply signal that the patent is invalid or unenforceable, spurring entry by other rivals. By contrast, in the Hatch-Waxman situation we discuss in this section, exclusion payments may have been attractive to both parties because of the unusual opportunity that Hatch-Waxman presented: When the would-be first generic entrant declines to enter the market (in exchange for an exclusion payment), until 2004 subsequent generic entrants were precluded from entering the market at all until after the 180-day generic exclusivity period had expired. Even since that time, the regulatory barriers to generic entry under Hatch-Waxman mean that excluding an approved generic from the market buys additional time during which the patentee has market exclusivity.

Transaction costs change the picture somewhat. If bringing and winning an infringement suit costs \$1 million, the patentee might be willing to pay the infringement defendant up to that much to exit the market because the cost of the settlement would be lower than the cost of an injunction.⁸⁰

(A). Overview of Hatch-Waxman Provisions

Conceptually, the problem of exclusion payments can arise whenever the patentee has an incentive to postpone determination of the validity of its patent. Practically, the problem of exclusion payments has arisen in antitrust law primarily in the pharmaceutical industry because of its unique patent rules. The 1984 Hatch-Waxman legislation attempted to balance the pioneer drug manufacturers' innovation incentives against the need to facilitate market entry by manufacturers of equivalent generic products.⁸¹ Because these concerns lay jointly in the domains of both the patent law and the law that governs FDA approval of new drug products, the Hatch-Waxman legislation included an extensive series of amendments to both the patent and federal drug statutes.⁸²

A major focal point of Hatch-Waxman was the prompt resolution of patent infringement disputes between pioneers and potential generic entrants.⁸³ Hatch-Waxman introduced three pertinent innovations: (1) a patent "listing" requirement directed to the pioneer,⁸⁴ (2) a 30-month stay of the FDA's approval of the generic product whenever a patentee sues an infringer,⁸⁵ and (3) a 180-day exclusivity period benefitting the first generic producer to enter the market once a patent expires.⁸⁶ Each of these affects the bargaining dynamic in modern pioneer/generic pharmaceutical patent litigation, and each can be criticized

an agreement from the infringement defendant that it not enter the market. The patentee could obtain precisely the same value by a license agreement given to the infringement defendant, whose value makes the joint production of the two firms worth \$600,000 a year to the patentee. In either case the patentee would obtain its expected value of \$600,000 a year from the patent. Litigation costs and market uncertainties would certainly complicate the calculus, but they would not change the basic principle.

⁸⁰Of course, the settlement would not resolve questions about the patent's validity or coverage, whereas the court's judgment would, making the settlement less valuable to society.

⁸¹See Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.). Tom Cotter has an excellent discussion of the details of Hatch-Waxman. See Thomas F. Cotter, Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley, 87 Minn. L. Rev. 1789 (2003); see also Marcy Lobanoff, Comment, Anti-Competitive Agreements Cloaked as "Settlements" Thwart the Purposes of the Hatch-Waxman Act, 50 Emory L.J. 1331, 1332-1337 (2001).

⁸²See §§ 101-105, 98 Stat. at 1585-1603.

⁸³See 21 U.S.C. § 355(j)(5).

⁸⁴See *id.* § 355(b)(2)(a).

⁸⁵See *id.* § 355(j)(B)(iii).

⁸⁶See *id.* § 355(j)(B)(iv).

as presenting opportunities for either unilateral anticompetitive behavior on the part of the pioneer or pioneer/generic collusion in the form of anticompetitive settlements.

When a pioneer drug manufacturer seeks FDA approval for a new product by filing a New Drug Application (NDA), the pioneer must list any patents having product or method-of-use claims that would be infringed by a generic producer.⁸⁷ Listing provides notice to potential generic producers, but it also presents pioneers with an opportunity to force a series of downstream consequences having the potential to hinder competition. Collateral disputes have now arisen over the “listability” of particular patents or types of patent claims.⁸⁸ After the Federal Circuit held in *Mylan v. Thompson* that there was no cause of action for delisting an improperly-listed drug on the Orange Book, Congress passed 21 U.S.C. § 355(j)(5)(C)(ii) to create a counterclaim to a patent infringement suit requiring the FDA to correct an improperly listed patent on the Orange Book.^{88.1} Such a challenge was at issue in *Caraco Pharmaceutical Laboratories v. Novo Nordisk*.^{88.2} The issue in that case was whether a method patent was properly listed on the Orange Book if it covered just one of multiple possible uses for a drug, even though the generic in that case sought to use a different method. The Federal Circuit held that it did,^{88.3} but the Supreme Court reversed. The Court held the generic could bring a claim for correction of the Orange Book where the patent was properly listed on the Orange Book but the listing should be narrowed to exclude the generic’s noninfringing use. The Court did not directly opine on antitrust matters, but it did characterize the use of overbroad listing codes in the Orange Book as “anticompetitive.”^{88.4}

One of the key downstream consequences of a patent listing in a pioneer’s NDA is the prospect that FDA approval of a competitor’s generic product will be stayed for 30 months.⁸⁹ A potential entrant into the generic market can secure FDA approval by filing an Abbreviated New Drug Application (ANDA), which asserts that the generic product is a bioequivalent of the pioneer product.⁹⁰ Where the pioneer’s product or method of use is the subject of patent protection, and the pioneer has listed the patents, the

⁸⁷NDA applicants must file

the patent number and expiration date of any patent which claims the drug for which the applicant submitted the application or which claims the method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

Id. § 355(b)(1). The FDA publishes this information in the “Orange Book.” See *id.* § 355(j)(7)(A)(iii).

⁸⁸See, e.g., *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1328-1333 (Fed. Cir. 2001). In *Mylan*, a generic drug applicant sought to delist a patent from the Orange Book. *Id.* at 1325. The court denied the request, however, finding no such cause of action exists “outside a properly filed patent case.” *Id.* at 1331-1333. For further discussion, see § 15.3c.

^{88.1}That section provides:

(ii) Counterclaim to infringement action

(I) In general

If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either-

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

^{88.2}132 S. Ct. 1670 (2012).

^{88.3}601 F.3d 1359, 1368 (Fed. Cir. 2010).

^{88.4}132 S. Ct. at 1678.

⁸⁹See 21 U.S.C. § 355(j)(5)(B)(iii).

⁹⁰*Id.* § 355(j)(2)(A)(iv).

generic's ANDA must also include one of four certifications concerning the impact of the pioneer's listed patents on the generic's proposed manufacturing activity.⁹¹ Of greatest relevance here is the Paragraph IV certification, under which the ANDA applicant asserts that the relevant patent is invalid or not infringed⁹² and provides a detailed notice (known as “2(B)(I) notice”) to the pioneer, including a detailed opinion supporting the assertions of invalidity or noninfringement.⁹³

When the generic makes a Paragraph IV certification, the pioneer has 45 days from the date of the 2(B)(i) notice to sue for infringement.⁹⁴ If the pioneer does not timely file such a suit, the ANDA approval “shall be made effective immediately.”⁹⁵ If the pioneer does timely file, ANDA approval is effective “upon the expiration of the 30-month period” beginning on the date of receipt of the (2)(B)(i) notice, although the court may order a shorter or longer period where “either party to the action failed to reasonably cooperate in expediting the action.”⁹⁶ If a court concludes in a final decision that the patent is invalid or not infringed prior to the expiration of the 30-month stay, ANDA approval is effective as of the date of that court decision.⁹⁷

The existence of a single 30-month stay materially affects the bargaining calculus between pioneer and generic in a patent infringement suit because it is the equivalent of an automatic preliminary injunction, which courts would be reluctant to issue in a normal patent suit. Further, until 2004 the Hatch-Waxman provisions created the potential for a pioneer to invoke multiple 30-month stays by successively listing new patent information in the Orange Book relevant to a given drug product.⁹⁸ The prospect of multiple 30-month stays presented an opportunity for “evergreening,” a form of anticompetitive behavior that does not exist in ordinary patent infringement litigation. Regulatory and legislative changes effective in 2004 deal effectively with the problem of multiple 30-month stays, both by giving a generic ANDA applicant sued for patent infringement the right to assert a counterclaim challenging the listing of information in the Orange Book⁹⁹ and by limiting patentees to a single 30-month stay for any given drug, regardless of the number of patents listed as covering that drug.¹⁰⁰

The final Hatch-Waxman innovation of relevance here—the 180-day exclusivity period—also may make pioneer/generic pharmaceutical patent settlements fundamentally different from other patent infringement settlements.¹⁰¹ Under the Hatch-Waxman legislation, after a first generic producer files an ANDA containing a Paragraph IV certification, subsequent ANDAs filed by other generic producers for

⁹¹*Id.* § 355(j)(2)(A)(vii).

⁹²*Id.* § 355(j)(2)(A)(vii)(IV).

⁹³*Id.* § 355(j)(2)(B)(i)-(ii); see also 21 C.F.R. §§ 314.50(i), 314.94(a)(12) (2002) (describing requirements for patent certifications by ANDA filers).

⁹⁴21 U.S.C. § 355(j)(5)(B)(iii). The filing of an ANDA “for a drug claimed in a patent or the use of which is claimed in a patent” is a technical act of infringement under the patent statute. 35 U.S.C. § 271(e)(2)(A).

⁹⁵21 U.S.C. § 355(j)(5)(B)(iii).

⁹⁶*Id.*

⁹⁷*Id.* § 355(j)(5)(B)(iii)(I).

⁹⁸The potential for multiple stays arises because multiple different patents might cover various aspects of a single commercial drug product. The pioneer might list a first patent, subsequently sue an ANDA filer, and trigger a 30-month stay of the ANDA. If the pioneer then lists new patent information, the cycle may be started again: The ANDA filer would be compelled to make another certification, the pioneer could sue, and the FDA would initiate another 30-month stay.

⁹⁹21 U.S.C. § 355(j)(5)(C)(2).

¹⁰⁰Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676-77, 21 C.F.R. pt. 314 (June 18, 2003).

¹⁰¹See Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act, Pub. L. No. 98-417, § 101, 98 Stat. 1585, 1589 (1984) (codified as amended at 21 U.S.C. § 355(j)(5)(B)(iv)).

the same drug product “shall be made effective not earlier than” 180 days after (1) the date on which the first generic begins marketing the generic product¹⁰² or (2) the date of a court decision holding the patent invalid or not infringed, whichever is earlier.¹⁰³

Until 1998, the FDA conditioned the 180-day market exclusivity period on the requirement that the first generic ANDA filer have successfully defended against a patent infringement suit.¹⁰⁴ In *Mova Pharmaceutical Corp. v. Shalala*, the D.C. Circuit struck down this practice.¹⁰⁵ The FDA now grants the exclusivity period to the first generic ANDA filer whether or not the pioneer has sued the generic for patent infringement.¹⁰⁶ Indeed, most grants of 180-day exclusivity today come not from successful challenges to patents but from generic companies that obtain entry rights through settlements, often settlements with cash payments attached.^{106.1}

The 180-day exclusivity period offers the potential for collusive settlement arrangements between pioneers and generics. A pioneer could initiate a patent infringement suit against a first generic ANDA filer and settle the litigation with an exclusion payment to the generic, under which the generic would delay commercialization of the generic product, thus postponing the commencement of the 180-day exclusivity period and locking other generics out of the market.¹⁰⁷ Until 2004, such an agreement could keep out other generics indefinitely, because until the first generic actually entered the market no others would have the right to do so. Congress changed the law effective in 2004 to provide that the first generic to file an ANDA is entitled to only 180 days of generic exclusivity and forfeits that exclusivity if it fails to enter the market within a reasonable time.¹⁰⁸ This new provision reduces, but certainly does not eliminate, the gains from anticompetitive settlements. Agreements that exclude generic competitors since that time can still delay generic entry, either directly (if the first ANDA filer agrees to an entry date and therefore can still obtain its generic exclusivity) or because the FDA approval process takes time, so that

¹⁰²21 U.S.C. § 355(j)(5)(B)(iv). More precisely, this is the date on which the Secretary of Health and Human Services receives notice of the first commercial marketing of the generic drug under the first generic's ANDA. *Id.*

¹⁰³*Id.* Before 2000, the FDA regulations provided that a court decision triggered the 180-day exclusivity period only if the decision was a “final judgment from which no appeal can be or has been taken.” 21 C.F.R. § 314.107(e)(1) (1999). Congress changed the law in 2003 so that the decision of a district court is sufficient to trigger the 180-day period.

¹⁰⁴21 C.F.R. § 314.107(c)(1).

¹⁰⁵140 F.3d 1060, 1066-1074 (D.C. Cir. 1998). See also *Granutec, Inc. v. Shalala*, 46 U.S.P.Q.2d (BNA) 1398, 1401 (4th Cir. 1998).

¹⁰⁶Guidance for Industry on 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act; Availability, 63 Fed. Reg. 37,890, 37,890-91 (July 13, 1998). Proposed regulations implementing this approach are still pending. See 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873, 42,874 (Aug. 6, 1999).

^{106.1}C. Scott Hemphill & Mark A. Lemley, Earning Exclusivity: Generic Incentives and the Hatch-Waxman Act, 77 Antitrust L.J. 947 (2011) (reporting results of an empirical study on the basis of 180-day generic exclusivity awards).

¹⁰⁷Other agreements are even more clearly anticompetitive. For example, an agreement by a patentee and a potential generic entrant that the patentee will pay the generic to continue the lawsuit—and thus the automatic stay of any generic entry—without ever prosecuting it to a conclusion is clearly anticompetitive and lacks even the redeeming virtue of ending an expensive litigation. Such an agreement can be condemned as illegal per se. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003).

¹⁰⁸21 U.S.C. § 355(j)(5)(D)(i)(I).

other generics will not be able to enter as quickly.^{108.1}

The Federal Trade Commission now requires disclosure of patent settlements so that it can evaluate them for anticompetitive effects. The government has prosecuted companies that failed to disclose their settlements.¹⁰⁹ According to an FTC study based on those reported settlements, out of 20 final settlement agreements resolving patent litigation between pioneers and first generic ANDA filers through 2001, 14 contained waiting period provisions—that is, provisions mandating that the generic wait for a specified period of time, ending on or before the date the patent expired, before entering the market.¹¹⁰ Nine of the agreements studied by the FTC involved payments from the pioneer to the generic.¹¹¹ Payments under the nine agreements ranged from \$1.75 million to \$132.5 million total.¹¹² An updated study of settlements filed during 2003 and 2004 found 14 agreements settling patent litigation, with none involving an exclusion payment, presumably because of antitrust scrutiny.¹¹³ But by 2005, as courts grew more and more lenient in their antitrust treatment,¹¹⁴ pharmaceutical companies were once again using exclusion payments. Three of 16 settlements in 2005, 7 of 10 in 2006, and 14 of 33 in 2007 involved such a payment. The numbers continued to increase as antitrust claims against exclusion payments foundered; 19 settlements in 2009, 31 settlements in 2010, 28 settlements in 2011, and 40 settlements in 2012 included exclusion payments.^{114.1}

(B). *Caselaw before Actavis*

To begin, it seems clear that exclusion payment settlements must be assessed on the antitrust merits. Some settling parties have argued that their settlement should be immune from antitrust scrutiny because it relates to a lawsuit, which is in turn a government petition. A variant of this argument holds that if the parties ask the judge to approve the settlement, that request cloaks the underlying settlement with immunity.

The problem with this argument is that the anticompetitive consequences of the exclusion payment flow from the agreement between the private parties, not from the result of the petition to the court or

^{108.1}For discussion, and a proposal to condition 180-day generic exclusivity on successful litigation by the generic, see C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Incentives and the Hatch-Waxman Act*, 77 *Antitrust L.J.* 947 (2011).

¹⁰⁹In 2007 Bristol-Myers pled guilty and paid a criminal fine for failing to report an agreement that involved a reverse payment settlement of a pharmaceutical patent infringement suit and an agreement by one firm to stay out of the market in exchange for a large payment. The conviction was for violation of the federal False Statements Act, 18 U.S.C. § 1001. The guilty plea is reported at <www.usdoj.gov/atr/public/press_releases/2007/223634.htm>.

¹¹⁰Federal Trade Commn. *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 26 (2002), <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

¹¹¹*Id.* at 25, <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

¹¹²*Id.* at 31-32, <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>. Although the sheer amount of the payment alone may seem sufficient to raise concerns about potential anticompetitive behavior, additional information would seem relevant as well—for example, the length of time over which the payout is being made (typically measured by the time between the agreement and patent expiration) and the value of the brand name product (measured, for example, in terms of the pioneer's net sales of the product annually). The FTC study includes such information for each of the nine agreements. *Id.*, <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

¹¹³<http://www.ftc.gov/opa/2005/01/drugsettlement.htm>.

¹¹⁴See § 7.4e2.

^{114.1}<http://www.ftc.gov/os/2011/10/1110mmaagree.pdf>. Even in 2011, equally many cases settled without any delay or exclusion payment (28), and another 100 settled with delayed entry but without a payment.

from any action by that court. To apply *Noerr* immunity to all settlement agreements would mark a major shift in the scope of antitrust law. As one commentator put it, the consequences would be “staggering...entire industries may be monopolized, prices fixed, and have their markets divided, without anyone being the wiser.”¹¹⁵ Not surprisingly, courts have generally rejected such claims.¹¹⁶ And the Supreme Court in *Actavis* clearly saw no reason to give settlements special immunity from antitrust scrutiny.

Court and agency decisions evaluating exclusion payments during the 2000s led to widely different outcomes, ranging from per se illegality to per se legality and including various sorts of rule of reason analysis in between. Some of this variation can be explained by the particular factual circumstances of the various cases, but there was also a split among the circuits about how to treat exclusion payments.

Per se analysis. The Sixth Circuit has applied that approach to Hatch-Waxman exclusion payments as well. In *In re Cardizem CD Antitrust Litigation*,¹¹⁸ the patentee Hoechst and the generic Andrx entered into an agreement during patent litigation under which Hoechst would pay Andrx \$10 million a quarter, in return for which Andrx would neither enter the market nor seek to prosecute the suit in which it was a defendant to a conclusion. The effect of the agreement was to delay the onset of the 180-day generic exclusivity period, since the parties agreed to extend rather than terminate the litigation, and therefore to delay indefinitely the entry of other generic competitors, who were required to wait until the expiration of Andrx's 180-day exclusivity. Andrx was ultimately paid nearly \$90 million under the agreement. The Sixth Circuit declared the agreement illegal *per se*. Similarly, the Federal Trade Commission imposed a rule of “presumptive” (though not per se) illegality in its decision in *In re Schering Plough Corp.*¹²²

Subsequent courts emphasized the particular facts of *Cardizem* in distinguishing its application of the per se rule. In particular, the fact that the agreement did *not* settle the lawsuit, but affirmatively required it to continue, made it clear that the goal of the agreement was not to reduce litigation costs but instead to take advantage of a flaw in the design of the regulatory system.^{121,2}

Rule of reason analysis; importance of patent validity. Other courts have proven more receptive to the arguments of pharmaceutical companies. *Valley Drug Co., Inc. v. Geneva Pharmaceuticals, Inc.*¹²⁷ refused to apply the per se rule to an exit payment settlement that seemed anticompetitive on its face. Abbott was the pioneer manufacturer of Hytrin, the name brand of a drug whose active ingredient was

¹¹⁵Raymond Ku, *Antitrust Immunity, the First Amendment and Settlements: Defining the Boundaries of the Right to Petition*, 33 Ind. L. Rev. 385, 388-89 (2000).

¹¹⁶See *Andrx Pharms., Inc. v. Biovail Corp.*, 256 F.3d 799 (D.C. Cir. 2001) (settlements not immune under *Noerr*); *In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 618 (E.D. Mich. 2000) (*Noerr* immunity did not shield agreements incidental to patent litigation), *aff'd*, 332 F.3d 896 (6th Cir. 2003); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003) (private settlement was not subject to *Noerr* immunity merely because it was submitted to a court for approval; the court seemed to confuse *Noerr* and state action immunity). *Cf. Andrx Pharms. v. Elan Corp.*, 421 F.3d 1227, 1235-36 (11th Cir. 2005) (applying *Noerr* to immunize Elan's patent infringement lawsuits but not its settlement of those suits). By contrast, the court in *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121 (E.D.N.Y. 2003) held that a petition by a generic manufacturer to the FDA to change a paragraph (iv) certification after a patent settlement triggered *Noerr* immunity. The court declined to decide whether the settlement agreement itself would be entitled to *Noerr* immunity. *Id.* at 135 n.11.

¹¹⁸332 F.3d 896 (6th Cir. 2003).

¹²²No. 9297 (F.T.C. Dec. 18, 2003), *rev'd*, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005). We discuss the Eleventh Circuit opinion below.

^{121,2}That fact pattern was also driving the other case to have applied per se illegality (or at least presumptive illegality), the D.C. Circuit's decision in *Andrx Pharms., Inc. v. Biovail Corp.*, 256 F.3d 799 (D.C. Cir. 2001).

¹²⁷344 F.3d 1294 (11th Cir. 2003).

terazosin. Its basic patent had expired but over the years Abbott had obtained additional patents for other forms of the terazosin compound and methods of preparing it. When generic makers Geneva and Zenith filed ANDAs on generic versions and sought delisting of Abbott's later patents, Abbott filed infringement claims. Zenith and Abbott then entered a settlement agreement under which Zenith promised not to pursue its delisting claim against Abbott and acknowledged the validity of Abbott's subsequent patents. In exchange, Abbott promised to pay Zenith a sum exceeding \$25 million per year for staying out of the terazosin market until a different generic manufacturer should enter. Abbott also entered an agreement with Geneva under which Abbott agreed to pay Geneva \$4.5 million monthly, and Geneva agreed not to market its generic terazosin pending the outcome of an infringement suit on the principal subsequent Abbott patent. The invalidity of that patent was established in a decision affirmed by the Federal Circuit.¹²⁸

The Eleventh Circuit reasoned from the premise that a valid patent gives its owner a right to exclude to the conclusion that the payment for exclusion was not an unwarranted extension of the patent.

The Eleventh Circuit did not conclude that the agreement in question was necessarily legal, however. Instead, the court concluded that the legality of the settlement agreement depended on whether the patentee would in fact have won the underlying patent suit. If the patentee would have won, the settlement did not exclude generic competition that should have been permitted. If the patentee would have lost, by contrast, a settlement that excludes the generic reduces competition and is therefore illegal.

The Eleventh Circuit moved even further away from a rule of per se illegality in reversing the FTC's decision in *Schering Plough Corp. v. FTC*.¹³⁴ There, the court concluded that "neither the rule of reason nor the per se analysis is appropriate in this context."¹³⁵ Instead, the court constructed a three-part test in which it looked at "(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."¹³⁶ Stated that way, the Eleventh Circuit's legal test does not seem dissimilar to the FTC's rule of reason approach. But the court diverged sharply from the FTC—and from its own prior decision in *Valley Labs*—in engaging in an all-but-conclusive presumption that an issued patent was valid. Because it presumed that a patent that had not yet been invalidated was necessarily valid, at least unless the patentee's infringement lawsuits were shams,¹³⁷ the court found no expansion beyond the proper legal scope of the patent.^{137.1} *Extreme deference; per se legality*. The Second and Federal Circuits have shown even more lenient treatment toward exclusion payments than the Eleventh Circuit. In *In re Tamoxifen Citrate Antitrust Litig.*,¹⁴² the patentee Zeneca had sued Barr for infringement of its breast cancer drug, but the district court held the patent invalid. While the case was pending on appeal, the parties settled, with the patentee agreeing to pay Barr and its supplier \$65 million and also give it a license to produce an authorized generic version of the drug, but only if the parties could collectively persuade the court to vacate the judgment of invalidity, which it ultimately did. The plaintiffs also alleged that Barr agreed to, and did, use its 180-day generic exclusivity to keep other ANDA filers from entering the market. Those subsequent ANDA filers, unable to rely on the vacated judgment of invalidity, ultimately lost their validity challenges against Zeneca's

¹²⁸ *Abbott Labs v. Geneva Pharms., Inc.*, 182 F.3d 1315 (Fed. Cir. 1999).

¹³⁴ 402 F.3d 1056 (11th Cir. 2005).

¹³⁵ *Id.* at 1065.

¹³⁶ *Id.* at 1066.

¹³⁷ *Id.* at 1068.

^{137.1} And indeed, district courts in the Eleventh Circuit have shown more deference to exclusion payments since *Schering-Plough*. While the district court on remand in *Valley Drug* inquired into who would have won the underlying patent suit, the district court in *In re AndroGel Antitrust Litig.*, 687 F. Supp. 2d 1371 (N.D. Ga. 2010) refused even to consider the likelihood that the patentee would have won the suit, and treated the fact of an exclusion payment as wholly irrelevant to an antitrust analysis.

¹⁴² 466 F.3d 187 (2d Cir. 2006).

patent.

Notwithstanding these facts, the district court granted Zeneca's Rule 12(b)(6) motion to dismiss a variety of antitrust challenges to the settlement, and the Second Circuit affirmed. The court created a virtually irrebuttable presumption: "so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product."¹⁴⁶ The result is that in the Second Circuit, exclusion payments are legal per se unless the underlying lawsuit was not only weak but a sham, a standard that is virtually impossible to surmount.¹⁴⁷

The Federal Circuit followed the Second Circuit's approach of extraordinary deference in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*,¹⁵³ affirming a grant of summary judgment for the defendant in a case in which the patentee paid \$398 million to exclude the generic competitor. The Federal Circuit announced that it was applying a rule of reason analysis.¹⁵⁴ It found "no evidence that the Agreements created a bottleneck on challenges to the '444 patent or otherwise restrained competition outside the 'exclusionary zone' of the patent."¹⁵⁵ So far, that analysis seems consistent with the Eleventh Circuit approach in *Valley Labs*. But the Federal Circuit departed from the rule of reason approach by limiting the inquiry into the merits of the underlying patent suit to the very limited question of "whether there was evidence of sham litigation or fraud before the PTO."¹⁵⁶

These courts put a very strong premium on the policy of encouraging settlement, something echoed by Chief Justice Roberts' dissent in *Actavis*. They worried that pharmaceutical companies would not be able to settle patent litigation without a reverse payment.

Quick Look. In *In re K-Dur Antitrust Litigation*,^{158.2} the Third Circuit canvassed all of the approaches described above, and rejected the Second/Federal Circuit approach as overly deferential.

Ultimately, the Third Circuit stopped short of a per se illegality standard, adopting instead a "quick look rule of reason analysis based on the economic realities of the reverse payment settlement."^{158.8} The court weighted the outcome of that quick look quite strongly toward a finding of illegality, however:

[T]he finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.

...

¹⁴⁶*Id.*

¹⁴⁷See § 11.3c (discussing the difficulty antitrust plaintiffs have in showing sham litigation to overcome *Noerr* immunity).

¹⁵³544 F.3d 1323 (Fed. Cir. 2008).

¹⁵⁴The case arose from a district court in the Second Circuit. The Federal Circuit normally applies regional circuit antitrust law. In this case, it cited the law of the Second Circuit but did not specify whether it was applying *Tamoxifen* as binding law or drawing its own legal conclusions. Resolution of this question will be important if future cases are appealed to the Federal Circuit from circuits that, unlike the Second Circuit, apply per se or full rule of reason analyses. For discussion of the issue, see § 5.3a.

¹⁵⁵*Id.* at 1332.

¹⁵⁶*Id.* at 1335.

^{158.2}*Id.*

^{158.8}*Id.* at *16.

We agree, moreover, with the FTC that there is no need to consider the merits of the underlying patent suit because “[a]bsent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.”^{158.9}

(C) Actavis

*Federal Trade Commission v. Actavis, Inc.*¹ involved a fairly typical reverse-payment scenario. Solvay Pharmaceuticals obtained a patent on AndroGel. Actavis and Paddock Laboratories both filed ANDA applications alleging that the patent was invalid. Solvay sued and obtained an automatic 30-month stay of Actavis’s ANDA approval. The FDA approved Actavis’s ANDA after the stay expired, while the case was pending, but the parties settled, with Actavis agreeing to delay entry for nine years in exchange for payments ranging from \$19-30 million each year; the other generics were also paid smaller amounts to drop their challenges. The generics also promised to help Solvay promote its brand-name drug, and the settling parties claimed that this marketing assistance was the reason for the payments, but the Federal Trade Commission alleged that those services had “little value” and that the “true point of the payments was to compensate the generics for agreeing not to compete.”²

The district court granted defendants’ motion to dismiss the FTC’s antitrust complaint, and the Eleventh Circuit affirmed, holding that that “absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.”³

The Supreme Court reversed, 5-3. In an opinion by Justice Breyer, the Court held that “reverse payment settlements . . . can sometimes violate the antitrust laws.”⁴ In so doing, the Court flatly rejected the “scope of the patent” test endorsed by the Second, Eleventh, and Federal Circuits:

Solvay’s patent, if valid and infringed, might have permitted it to charge drug prices sufficient to recoup the reverse settlement payments it agreed to make to its potential generic competitors. And we are willing to take this fact as evidence that the agreement’s “anticompetitive effects fall within the scope of the exclusionary potential of the patent.” [677 F.3d, at 1312](#). But we do not agree that that fact, or characterization, can immunize the agreement from antitrust attack.⁵

The Court emphasized that this “scope of the patent” test would apply only to patents known to be valid and infringed. But that was the very question the settlement avoided resolving:

^{158.9}*Id.*

¹ 570 U.S. ___, 133 S.Ct. 2223 (2013).

² *Id.* at 2230.

³ [FTC v. Watson Pharmaceuticals, Inc.](#), 677 F.3d 1298, 1312 (11th Cir. 2012).

⁴ *Actavis*, 570 U.S. at ___, 133 S.Ct. at 2227.

⁵ *Id.* at 2230.

The patent here may or may not be valid, and may or may not be infringed. . . . But an *invalidated* patent carries with it no such right. And even a valid patent confers no right to exclude products or processes that do not actually infringe.⁶

Importantly, the Court made it clear that the relevant question was not merely what rights patent law would have conferred. “[I]t would be incongruous to determine antitrust legality by measuring the settlement’s anticompetitive effects solely against patent policy, rather than by measuring them against precompetitive antitrust policies as well.”⁷ Rather, both antitrust and patent policy were relevant to determining the proper “scope of the patent monopoly – and consequently antitrust immunity – that is conferred by a patent. . . . Whether a particular restraint lies beyond the limits of the patent monopoly is a *conclusion* that flows from [traditional antitrust] analysis and not . . . its starting point.”⁸ The Court cited a number of its precedents applying antitrust scrutiny to patent-related settlements, observing that those cases “seek to accommodate patent and antitrust policies, finding challenged terms and conditions unlawful unless patent law policy offsets the antitrust law policy strongly favoring competition.”⁹

The Court acknowledged the argument made by Chief Justice Roberts’ dissent (and the Eleventh Circuit) that the “strong interest in settlement” justified deference to reverse-payment settlements. But it found that argument insufficient to drive the result, for several reasons. First, the Court emphasized the settlement’s “potential for genuine adverse effects on competition.”¹⁰ As the Court explained,

The payment in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product. . . .

But settlement on the terms said by the FTC to be at issue here—payment in return for staying out of the market—simply keeps prices at patentee-set levels, potentially producing the full patent-related [] monopoly return while dividing that return between the challenged patentee and the patent challenger. The patentee and the challenger gain; the consumer loses. Indeed, there are indications that patentees sometimes pay a generic challenger a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market.¹¹

And while in other markets such a sizeable payment might signal weakness and invite entry by other competitors, the nature of the Hatch-Waxman Act makes that unlikely, both because the settling first generic retains 180 days of generic exclusivity and because the subsequent entrant will be subject to an automatic 30-month stay.¹²

The Court acknowledged that there might be legitimate justifications for a reverse payment; we

⁶ *Id.* at 2231 (emphasis in original).

⁷ *Id.*

⁸ *Id.* at 2231-32 (emphasis in original).

⁹ *Id.* at 2233. Chief Justice Roberts, dissenting, challenged the Court’s interpretation of those precedents, arguing that none of them involved the situation presented here – the settlement of a suit over a single patent with market division, as opposed to a patent pool or price-fixing agreement. *Id.* at 2239-43 (Roberts, C.J., dissenting).

¹⁰ *Id.* at 2234.

¹¹ *Id.* at 2234-35.

¹² *Id.* at 2235.

discuss this in more detail in section D, below. But that wasn't a reason to create an exception from the normal rules of antitrust law; defendants will be free to offer those justifications in the course of an antitrust case.¹³ Notably, the Court expressed skepticism of many of those reasons:

Although the parties may have reasons to prefer settlements that include reverse payments, the relevant antitrust question is: What are those reasons? If the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement.¹⁴

To apply the scope of the patent test to bar any challenge “throws the baby out with the bath water, and there is no need to take that drastic step.”¹⁵ That is particularly true because the Court’s rule “does not prevent litigating parties from settling their lawsuit. They may, as in other industries, settle in other ways, for example by allowing the generic manufacturer to enter the patentee’s market prior to the patent’s expiration, without the patentee paying the challenger to stay out prior to that point.”¹⁶

Despite concluding that reverse payments will often be anticompetitive, the Court rejected the quick look approach adopted by the Third Circuit and proposed by the Federal Trade Commission in favor of a rule of reason analysis. In so doing, however, the Court was careful to note that this rule of reason analysis need not be as full-blown as a normal antitrust case. Rather, the Court left to the lower courts the task of

structur[ing] antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences.¹⁷

We turn in the next section to how courts might accomplish that task.

(D) Applying the Rule of Reason to the Problem of Pharmaceutical Settlements

The question then becomes how to apply the rule of reason inquiry envisioned by the Supreme Court in *Actavis*. In the paragraphs that follow, we suggest how we believe antitrust should treat exclusion payments in light of the *Actavis* decision and the economics of pharmaceutical patent litigation.

In the typical Hatch-Waxman case involving a large exclusion payment, the rule of reason as traditionally conceived under antitrust law will not be a fruitful avenue of inquiry. The very fact that the pioneer finds it worthwhile to pay a large exclusion payment tends to establish market power.¹⁶⁵ It also

¹³ *Id.* at 2236.

¹⁴ *Id.* at 2237.

¹⁵ *Id.* at 2236.

¹⁶ *Id.* at 2237.

¹⁷ *Id.* at 2238.

¹⁶⁵ *Actavis*, 133 S.Ct. at 2236 (making this point). For example, a pioneer’s willingness to pay 10 percent of its profits as an exclusion payment to a generic rival suggests that the pioneer’s profit-maximizing price is at least 10 percent above its costs. That market power may well have been legally conferred by an IP right, but the validity of that right is the very subject at issue in a settlement case. It is

suggests some inherent uncertainty as to the validity or scope of the patent; a patentee that is certain of winning will not pay anything more than its anticipated remaining legal fees in exchange for an agreement by a generic to exit the market.¹⁶⁶ The very fact of that uncertainty suggests that exclusion payments are anticompetitive—that on average such agreements exclude at least some generics that in fact had a legal right to compete. The reason the patentee is willing to make a payment that exceeds its litigation costs is precisely because the settlement will permit it to exclude competition from the market, whereas if it went to trial there is a chance that the patent would be held invalid or not infringed and the market would become competitive. On expectation, the patentee is paying for an advantage that it could not get if it went to trial.¹⁷³

The *Actavis* opinion contains a number of strong hints that the Court understands this, and does not intend the rule of reason to be unbounded or to allow settling parties to justify their conduct on the ground that it acquired certainty. Indeed, Tom Cotter suggests that “[i]n reality, the Court appears to have all but in name adopted the presumptive illegality approach it purported to reject.”¹⁸

First, the Court found the amount of the payment quite significant. Large payments, it suggested, could themselves be “strong evidence” of an antitrust violation:

The rationale behind a payment of this size cannot in every case be supported by traditional settlement considerations. The payment may instead provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim¹⁹ with a share of its monopoly profits that would otherwise be lost in the competitive market.

Indeed, the Court seemed to think that evidence of a sufficiently large payment was itself enough to prove the anticompetitive nature of a settlement:

An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness. The owner of

also no answer to say that judges lack significant experience with exclusion payments, and as a result these should be governed by the full rule of reason. See Morse, *supra* note 87, at 361-362 (arguing for a rule of reason approach in most cases). Consider, for example, *In re Schering-Plough Corp.*, in which the ALJ applied the rule of reason because judges lacked experience with Hatch-Waxman-style exclusion payments and dismissed the complaint. See No. 9297, slip op. at 98 (June 27, 2002) (initial decision), available at <http://www.ftc.gov/os/2002/07/scheringinitialdecisionp2.pdf>. The “judicial experience” argument runs to classes of restraints, not to particular products. An exclusion payment is in fact a type of naked horizontal market division agreement, which have been unlawful for a long time. For example, if a group of skateboard manufacturers should fix prices, one would not say that judicial experience with price fixing in skateboards is very limited, so the rule of reason should be applied.

¹⁶⁶See, e.g., Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 *Rand J. Econ.* 391 (2003); Cotter, note 124, at 1806 tbl.1.

¹⁷³Cf. George L. Priest, *Cartels and Patent License Arrangements*, 20 *J.L. & Econ.* 309, 327 (1977) (arguing that rational patentees won't reduce the royalty below zero unless they are cartelizing an industry). It is true, of course, that some patents that go to trial will be held valid and infringed, and therefore the patentee will keep its monopoly. But the anticompetitive harm comes from the fact that the settlement forecloses the incremental chance that the market would be competitive. Significantly, it is this very foreclosure that makes exclusion payments greater than the cost of litigation rational.

¹⁸Thomas F. Cotter, *FTC v. Actavis, Inc.: When is the Rule of Reason Not the Rule of Reason?*, 15 *Minn. J. L., Sci. & Tech.* (forthcoming 2013).

¹⁹*Id.* at 2235.

a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm. In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness . . .²⁰

For this reason, the Court concluded that “it is normally not necessary to litigate patent validity to answer the antitrust question.”²¹ The size of the payment stands in for what would otherwise be an unworkable reexamination of the underlying patent merits. It “provide[s] a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.”²²

Second, when the Court considered (at two different points in the opinion) what sorts of justifications the settling parties might offer for a reverse payment, it pointed to only two: the size of the payment and whether the payment was for something other than delayed entry.²³ Notably, in both cases, the Court's discussion of the size of the reverse payment focused on “its scale in relation to the payor's anticipated future litigation costs,”²⁴ not to risk aversion or the patentee's desire to convert an uncertain patent right into a certain one without litigation.²⁵ While the Court was careful to note that “[t]here may be other justifications,”²⁶ it did not see the elimination of the risk of invalidity as one of those justifications. To the contrary, the Court emphasized the importance to the public of weeding out bad patents. It rejected the dissent's call for immunity from antitrust scrutiny, saying that “[i]t would be difficult to reconcile the proposed right with the patent-related policy of eliminating unwarranted patent grants so the public will not “continually be required to pay tribute to would-be monopolists without need or justification.”²⁷

The Court's repeated references to the size of the payment in relation to litigation costs as the critical consideration, coupled with multiple comments indicating that the validity of the patent would not ordinarily be at issue and statements in Part III that a rule of reason analysis need not consider every argument, lead us to believe that a rule of reason analysis under *Actavis* will be simpler and more structured than a normal antitrust rule of reason case. The plaintiff may not need to show market power; the Court seemed to think market power could be presumed from the nature of the settlement and the regulatory framework. Nor would a court have to look very far for anticompetitive effect; the reverse

²⁰ *Id.* at 2236-37.

²¹ *Id.* at 2236.

²² *Id.* at 2236-37.

²³ “The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement. That payment may reflect compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item. There may be other justifications. Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.” *Id.* See also *id.* at 2237 (“the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.”).

²⁴ *Id.* at 2237.

²⁵ *Id.* at 2236 (“The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement.”); *id.* (“Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern”).

²⁶ *Id.*

²⁷ *Actavis*, 133 S.Ct. at 2233 (quoting [*Lear, Inc. v. Adkins*, 395 U.S. 653, 670 \(1969\)](#)).

payment by its nature had such an effect, the Court suggested.²⁸ So the focus of a rule of reason case after *Actavis* is likely to be on justifications for the settlement. Courts should look for some reason to think that a reverse payment had something other than its ordinary effect of persuading the generic to delay entry or stay off the market altogether. A payment to avoid expected future litigation costs might suffice, or a payment that was for something other than delay, such as a co-branding deal.

A harder question is whether the settling parties should be entitled to introduce evidence that the patent was in fact valid. It seems clear that proof of invalidity or noninfringement is no longer required to make out an antitrust violation. But what if the patent was later held valid in subsequent patent litigation against other parties? It might seem logical that a later determination of validity (or invalidity) would determine whether the settlement was anticompetitive. In fact, however, decisions prior to *Actavis* have made clear that the right time for assessing the competitive effects of the settlement is at the time of settlement, not afterwards. In *Valley Drug*, for example, the court concluded that the fact that the patents were later found invalid did not establish per se illegality, because at the time the agreements were formed, invalidity had not been finally established. We have no quarrel with that proposition and agree with the court's conclusion "that exposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid would undermine the patent incentives."²⁹ The right analysis for exclusion settlements is based on the ex ante assessment of the patent's validity, not on how the patent ultimately fares ex post in the courts. Many settlement agreements settle disputes on patents that are subsequently found invalid. The problematic thing about large exit payments to infringement defendants is that they raise a strong inference that the parties believed ex ante the patent is invalid. Thus, we are skeptical that subsequent evidence of validity or invalidity ought to carry much weight in the rule of reason inquiry. Certainly the *Actavis* Court did not think it necessary to inquire into validity.

Finally, courts will have to consider how large a payment will suffice to demonstrate the anticompetitive nature of a reverse payment settlement. We believe that the settling parties can defend by showing that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit.¹⁷⁴ The Court's references to the size of the payment were not measured relative to the patentee's expected profits, but rather to litigation expenses. Thus, the Court thought that a settlement might be legitimate if it "amount[ed] to no more than a rough approximation of the litigation expenses saved through the settlement."³⁰ A payment in excess of that amount is a payment for something. And if it is not to save litigation costs or to buy some other legitimate service from the generic, it must be to delay generic entry relative to what the parties expected would have happened had the case gone to trial.

The definition of litigation costs will also matter in practice. We think they should be limited to a good faith estimate of the out-of-pocket costs and attorneys' fees the patentee could expect to pay between the time of the settlement and the time the case was concluded. Although Robert Willig and John

²⁸ For discussion of those anticompetitive effects, see Herbert Hovenkamp, *Antitrust Scrutiny of Anticompetitive Patent Settlements: the Supreme Court's Actavis Decision* (working paper 2013).

²⁹ *Valley Drug*, 344 F.3d 1294 (11th Cir. 2003).

¹⁷⁴ See Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 *Antitrust Bull.* 491, 534-538 (2002); Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 *Mich. L. Rev.* 37 (2009); cf. Crane, note 169, at 779-796 (arguing that antitrust should permit such settlements when the ex ante success of the patent infringement suit is high and prohibit them when the ex ante success is low).

³⁰ *Actavis*, 133 S.Ct. at 2236; see also *id.* at 2237 ("Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern").

Bigelow have suggested that the value of uncertainty could be included in “litigation costs,”³¹ we think this impermissibly brings in the value of certain exclusion based on a doubtful patent under the rubric of litigation expenses. The *Actavis* Court viewed buying certainty as an anticompetitive aspect of reverse payment settlements, not as a justification; it would surely not accept elimination of that uncertainty as a “litigation cost.”³²

Finally, we think it important that the court make at least some limited inquiry into the merits of a settlement that requires the defendant to exit the market. If exclusion payments are illegal, the parties will have an incentive to conceal those payments, perhaps by turning them into noncash compensation (the patentee's forbearance from price competition in a separate market, for example). If the patent lawsuit is a sham, and the accused infringer still agrees to leave the market without a substantial exclusion payment, it is worth making sure there isn't another payment hidden in the transaction. This oversight necessarily requires some inquiry into the merits of the IP suit, but we think it need not be particularly searching. The goal is merely to ensure that there is a legitimate dispute being settled.^{174.1}

Actavis itself is an example of such a case. The settling parties alleged that the payment was for ancillary marketing services provided by the generic; the FTC disputed that and claimed that those services were not worth the money paid. The *Schering Plough* case was similarly complicated by the fact that the patentee's payment not only settled a validity dispute but also purchased another drug from the payee. To be evidence of invalidity in this context, a payment must exceed the fair market value of the drug being purchased. The evidence before the ALJ in *Schering Plough* was disputed.¹⁴⁰ But the complexity here arguably results from the deliberate effort of the settling parties to obfuscate the nature of the settlement by bundling together transactions that could easily be separated. Given the increasing tendency of settling parties to complicate their settlements to dissuade antitrust scrutiny, courts might reasonably place the burden on the settling parties to demonstrate how value should be allocated among the various portions of the transaction in cases like *Schering*.¹⁴¹

The legitimate exclusion value of a pharmaceutical patent is the power it actually confers over competition, which is in turn a function of the scope of the patent and its chance of being held valid. What the pharmaceutical patentees who agree to exclusion payments seek is something more: a guaranteed insulation from competition, without the risk that the patent is held invalid. IP policy does not offer such a guarantee and does not immunize from antitrust scrutiny those who seek it by entering into agreements

³¹ Robert D. Willig & John P. Bigelow, Antitrust Policy Towards Agreements That Settle Patent Litigation, 41 J. Econ. Lit. (2003).

³² *Actavis*, 133 S.Ct. at 2236 (“The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm.”).

^{174.1} Of course, if the parties can prove that there is no payment in exchange for exclusion or entry delay, *Actavis* would not apply. We discuss such cases in the next section.

¹⁴⁰ The question of separate business deals as “payments” for exclusion also arose in *FTC v. Warner Chilcott Holdings Co.*, 2006 WL 3302862 (D.D.C. Oct. 23, 2006), where the FTC and the defendant entered into a stipulated preliminary injunction forbidding Warner Chilcott from settling patent cases by providing the defendant with anything of value, including a separate supply agreement.

¹⁴¹ C. Scott Hemphill, An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition, 109 Colum. L. Rev. 629 (2009) (discussing the ways in which introduced complexity interferes with antitrust enforcement against settlement disputes). Hemphill argues for a ban on “complex” settlements, but we don’t see how that would work. The parties could always enter into separate side agreements. Courts must be willing to assess the legitimacy of side deals that purport to justify a payment.

that exclude potential competitors.^{178.1}

(E) *Agreements to Delay Entry*

Another alternative to exclusion payments is for the parties to settle a patent dispute by delaying entry by the generic. A stipulated injunction that lasts for less than the term of the patent is more likely to reflect the uncertain outcomes of patent litigation. For example, if a patent with ten years of term remaining is 50 percent likely to be held invalid, the parties might settle the case by agreeing that the generic will not enter for a specified number of years but then will be able to enter without paying a royalty.¹⁷⁹ The parties have effectively split the uncertainty costs of the litigation.¹⁸⁰ More important, assuming delayed entry is not coupled with an exclusion payment, it does not align the incentives of pioneer and generic litigants: Generics will want the delay to be as short as possible, and patentees to make the delay as long as possible. This means that we can expect that an agreement to delay entry reflects the parties' joint assessment of the likely outcome of the litigation. A delayed entry agreement therefore allows the parties to capture the economic significance of uncertainty as to patent outcome.¹⁸¹

As a result, we think courts ordinarily should not object to a delayed-entry settlement not induced by an exclusion payment, because it is likely to be an estimate of the expected outcome by the parties with the best information about that outcome.¹⁸² Indeed, the Supreme Court endorsed such settlements in dictum in *Actavis*,³³ offering them as an alternative to the reverse-payment settlements it found problematic.³³ Several caveats are necessary, however. First, delayed entry is an efficient solution only if it is not coupled with any form of exclusion payment. If a pioneer pays a generic to delay entry, the likelihood is that the delay does *not* in fact represent the expected outcome of litigation but rather has

^{178.1}By contrast, if the patent is actually determined to be valid and infringed, the subsequent exclusion of generic competition results from that conclusion, not from a settlement. *In re Plavix Indirect Purchaser Antitrust Litig.*, 2011 WL 335034 (S.D. Ohio Jan. 31, 2011) (“To the extent a patent is valid – and the Federal Circuit has affirmed the validity of the ‘265 patent and the USPTO has repeatedly declined to re-review it—a patent lawfully excludes competition.... Plaintiffs’ alleged injury—paying ‘artificially inflated prices for Plavix’— derives from the lack of access to a generic substitute caused by the court-ordered injunctions barring sales of a generic...”).

¹⁷⁹For endorsement of such an approach as procompetitive, see Willig & Bigelow, *supra* note 173.

¹⁸⁰Actually, the determination of the length of the delay is a bit more complicated than suggested in the text. First, the relevant period to be divided should begin when the trial would end, or when the 30-month stay would end, whichever is earlier; the generic couldn't enter before that date anyway. Second, because of the time value of money, the first five years of a ten-year period will provide more than 50 percent of the expected return over that period. The real calculation of the efficient delay will need to take into account the discount rate.

¹⁸¹O'Rourke and Brodley also endorse delayed entry as an alternative to exclusion payments. See Joseph F. Brodley & Maureen A. O'Rourke, Patent Settlement Agreements, Antitrust, Summer 2002, at 53, 55; Maureen A. O'Rourke & Joseph Brodley, An Incentives Approach to Patent Settlements, 87 Minn. L. Rev. 1767, 1786-1787 (2003).

¹⁸²See, e.g., *In re Lamictal Direct Purchaser Antitrust Litig.*, 2012 WL 6725580 (D.N.J. Dec. 6, 2012) (holding that a mere agreement to delay entry without a payment was not illegal; granting a motion to dismiss). For a more skeptical view of settlements that delay entry, even without a payment, see C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553 (2006). Hemphill's argument is that the fact of 180-day generic exclusivity will incline settling generics to delay entry longer than would be ideal.

³³ *Actavis*, 133 S.Ct. at 2237.

been biased toward later entry by the payment. Second, if the delayed-entry settlement has the effect of bottling up other entrants, for example by allowing the generic to “park” its 180-day exclusivity, it may distort competition even without an exclusion payment.^{182.1}

Finally, there is always a risk that the parties will successfully conceal an exclusion payment, for example by agreeing under the table that the parties will cartelize the industry after entry. For example, in *In re Skelaxin (Metaxalone) Antitrust Litigation*, the defendants claimed that there was no exclusion payment associated with the settlement. The court refused to dismiss the antitrust case, however, finding evidence that suggested a secret payment in association with the settlement, including secret meetings and alleged statements that the patentee intended to compensate generic companies with whom it was then in litigation.³⁴ To prevent this risk, courts should engage in at least some scrutiny of delayed entry settlements that do not have an apparent payment to ensure that the IP right is not a mere sham employed to conceal what is essentially a cartel.¹⁸³

^{182.1}For an argument that generics who settle paragraph (IV) challenges should not be allowed to maintain 180-day generic exclusivity, see C. Scott Hemphill & Mark A. Lemley, Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act, 77 Antitrust L.J. 947 (2011).

³⁴*In re Skelaxin (Metaxalone) Antitrust Litig.*, 2013 WL 2181185 (E.D. Tenn. May 20, 2013).

¹⁸³Courts do this already in the context of patent pools and cross-license agreements. See § 34.4a1. O'Rourke and Brodley worry that tests of this sort are indeterminate, O'Rourke & Brodley, *supra* note 21, at 1781-1782, but we don't see a good alternative.