
Hatch-Waxman Act — Reverse-Payment Settlements —
FTC v. Actavis, Inc.

Pharmaceutical development is an uncertain business. The process is long and laborious, resulting in research costs that are substantially higher than in other industries.¹ The vast majority of tested drugs are never approved for patient use, and most of those that are approved fail to generate any profit for their creators.² Because of the high costs of bringing a new drug to market, pharmaceutical manufacturers rely on the patent system to allow them to recoup their expenses. A patent grants a new drug's developer a period of exclusivity during which the brand-name drug can dominate the market at monopoly prices.³ Pharmaceutical developers have gone to great lengths to extend this period of exclusivity, at times resorting to questionable practices in order to generate higher profits from successful drugs.⁴ Success breeds competition, however, and generic drug manufacturers frequently seek to enter the market by piggybacking on the research efforts of the original developer.⁵ Rather than exposing their patents to the uncertainty of litigation, developers reach settlement agreements with generic drug manufacturers under which the developers will pay the generics to drop their patent challenges and stay out of the market during the lifetime of the patent.⁶ Last Term, in *FTC v. Actavis, Inc.*,⁷ the Supreme Court held that these “reverse-payment” settlements are subject to challenge under federal antitrust laws.⁸ Although aspects of the pharmaceutical settlement system create troubling incentives that may encourage anticompetitive cooperation, the Supreme Court's decision may be difficult to administer and may lead to uncertainty regarding what types of settlement agreements are permissible.

¹ Bret Dickey, Jonathan Orszag & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 367, 369 (2010). In order to account for failed research, some commentators have compared the total cost of research and development with the number of drugs approved and suggested that the actual cost of bringing a new drug to market is at least \$3 billion and can rise as high as \$12 billion. See Matthew Herper, *The Truly Staggering Cost of Inventing New Drugs*, FORBES (Feb. 10, 2012, 7:41 AM), <http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs>.

² See Dickey, Orszag & Tyson, *supra* note 1, at 369.

³ See *id.* at 389–90.

⁴ For example, developers adopted a strategy known as “evergreening,” in which they obtained multiple patents on the same product in order to reset the clock on the exclusivity period. Another strategy was to make minor changes to their drugs in order to require generics to reapply for FDA approval. These particular procedural schemes have been largely ended by congressional action. See C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 959–62 (2011).

⁵ Dickey, Orszag & Tyson, *supra* note 1, at 389–90.

⁶ *Id.*

⁷ 133 S. Ct. 2223 (2013).

⁸ *Id.* at 2230.

Pharmaceutical drugs cannot be sold in the United States until they have received approval from the Food and Drug Administration (FDA).⁹ Novel drugs must go through a period of rigorous testing and disclosure, during which the developer must demonstrate that the drug is both safe and effective.¹⁰ Once a pharmaceutical product has been approved, the FDA follows a streamlined process for approving bio-equivalent drugs.¹¹ This streamlined process allows generic manufacturers to bring their products to market without duplicating the expensive research and testing that the original drug underwent and is intended to facilitate the entry of generic drugs and the consequent decrease in the price of medicine.¹² Under the Hatch-Waxman Act,¹³ the generic manufacturer must make one of four certifications: (1) that the original manufacturer failed to patent the drug, (2) that the patent has expired or (3) will expire, or (4) that the patent is either invalid or not infringed by the generic.¹⁴ This last certification is known as a Paragraph IV certification, and there are numerous incentives for being the first generic to make such a claim, the most important of which is a 180-day exclusivity period after which no other similar generic drug can receive FDA approval.¹⁵ A pharmaceutical developer faced with a Paragraph IV certification is typically granted a thirty-month stay of the generic's application, during which the developer can attempt to demonstrate the validity and applicability of the patent by pursuing an infringement action against the generic manufacturer.¹⁶

In 1995, Solvay Pharmaceuticals entered into a licensing agreement with Besins Healthcare under which Solvay would market a topical synthetic testosterone product, AndroGel, in the United States.¹⁷ Although the patent for the synthetic testosterone compound had expired, Solvay applied for and received a patent for the new gel formulation of the drug.¹⁸ AndroGel received FDA approval in 2000 and

⁹ *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1302 (11th Cir. 2012) (citing 21 U.S.C. § 355(a) (2006 & Supp. V 2011)).

¹⁰ Dickey, Orszag & Tyson, *supra* note 1, at 371.

¹¹ *Id.* at 369–72.

¹² *Id.* at 371–72.

¹³ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of the U.S. Code).

¹⁴ Dickey, Orszag & Tyson, *supra* note 1, at 372. This Act provides patent holders with extended protections while creating a streamlined process through which generic drug manufacturers can challenge weak patents. See Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 *FOOD & DRUG L.J.* 417, 418 (2011).

¹⁵ Dickey, Orszag & Tyson, *supra* note 1, at 372–73.

¹⁶ *Id.* at 373.

¹⁷ *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1303–04 (11th Cir. 2012).

¹⁸ *Id.* at 1304. The patent was granted in 2003 and expires in 2020. *Id.*

generated nearly \$2 billion in sales over the next seven years.¹⁹ In May 2003, Watson Pharmaceuticals and Paddock Laboratories filed for FDA approval for generic versions of AndroGel under the streamlined process.²⁰ Both manufacturers certified that Solvay's patent was either invalid or would not be infringed; Solvay immediately filed patent infringement suits against both manufacturers in the Northern District of Georgia.²¹ After extensive discovery, the generic manufacturers filed summary judgment motions asking the court to rule on the validity of the patent.²² Faced with the potential loss of 90% of its sales and \$125 million in yearly profits if the summary judgment motions were granted, Solvay entered into a series of settlement agreements with Watson and Paddock.²³ Under these agreements, the generic manufacturers agreed to refrain from bringing generic versions of AndroGel to market for several years, to promote AndroGel to doctors, and to provide backup manufacturing capacity.²⁴ In return, Solvay compensated the generics with payments potentially exceeding \$300 million.²⁵

After the parties settled, the Federal Trade Commission (FTC) filed an antitrust suit alleging that the settlement agreements were unlawful agreements not to compete.²⁶ The FTC argued that Solvay's patent was weak and that Solvay and the generics had entered into the agreement in order to artificially extend Solvay's AndroGel monopoly, resulting in greater profits for the drug manufacturers and higher prices for consumers.²⁷ The drug manufacturers moved to dismiss for failure to state a claim on the grounds that the FTC had not alleged that the settlement exceeded the scope of the patent and that reverse-payment settlements were immune from antitrust attack so long as they did not cross that threshold.²⁸ The district court agreed with the manufacturers and dismissed the complaint.²⁹ The FTC appealed.³⁰

The Eleventh Circuit affirmed.³¹ Writing for a unanimous panel, Judge Carnes³² reviewed the circuit's reverse-payment precedent and

¹⁹ *Id.*

²⁰ *Id.* Watson filed first; Paddock partnered with Par Pharmaceutical Companies under an agreement in which Par would share the costs of the suit in exchange for a share of the profits generated by the generic (or by the settlement). *Id.*

²¹ *Id.*

²² *Id.*

²³ *Id.* at 1305.

²⁴ *Id.*

²⁵ *Id.* Aspects of the settlement depended on AndroGel's sales figures. *Id.*

²⁶ *Id.* The suit was heard in the Northern District of Georgia. *Id.*

²⁷ *Id.*

²⁸ *Id.* at 1306.

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.* at 1315.

³² Judges Kravitch and Farris joined Judge Carnes.

determined that any settlement agreement “within the scope of the exclusionary potential of the patent” is immune from antitrust liability.³³ Judge Carnes noted that although these agreements might be anticompetitive under traditional antitrust analysis, this analysis is not appropriate in a situation where a party holds a patent: “[A] patent conveys the right to ‘cripple competition.’”³⁴ In closing, Judge Carnes emphasized that the FTC was asking courts to engage in the “turducken task” of “deciding a patent case within an antitrust case about the settlement of the patent case,” a prospect the Eleventh Circuit found unpalatable.³⁵ Judge Carnes instead found that the agreement did not exceed the exclusionary scope of the patent and that antitrust principles therefore did not apply.³⁶

The Supreme Court reversed.³⁷ Writing for the Court, Justice Breyer³⁸ accepted that the anticompetitive impact of the settlement agreement fell within the scope of the patent, but declared that the agreement could nonetheless be attacked under federal antitrust laws.³⁹ Although a valid patent allows the patent holder to exclude infringing competitors from the market, the patent at issue “may or may not be valid, and may or may not be infringed.”⁴⁰ Justice Breyer, troubled by the “unusual” structure of a settlement in which the plain-

³³ *Watson Pharm.*, 677 F.3d at 1308–09 (quoting *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1311 (11th Cir. 2003)) (internal quotation marks omitted). Judge Carnes cited three previous Eleventh Circuit cases to demonstrate the broad antitrust immunity granted to patent settlements. In *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003) a reverse payment was challenged at least in part because the patent was later invalidated; plaintiffs asserted that this invalidation meant that the alleged patentee never had any patent rights. *Id.* at 1308 (citing *Valley Drug*, 344 F.3d at 1306). The Eleventh Circuit rejected that assertion, explaining that “[t]he mere subsequent invalidity of the patent does not render the patent irrelevant to the appropriate antitrust analysis.” *Id.* at 1308 (quoting *Valley Drug*, 344 F.3d at 1306–07) (internal quotation marks omitted). In *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), the Eleventh Circuit rejected the FTC’s contention that Schering-Plough had overpaid generic manufacturers in an effort to extend its monopoly, noting that patent litigation was “certain[] to be a bitter and prolonged process,” *Watson Pharm.*, 677 F.3d at 1310 (alteration in original) (quoting *Schering-Plough*, 402 F.3d at 1072) (internal quotation marks omitted), and that “[t]he size of the payment . . . should not dictate the availability of a settlement remedy,” *id.* (omission in original) (quoting *Schering-Plough*, 402 F.3d at 1075) (internal quotation marks omitted). In *Andrx Pharmaceuticals, Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005), however, the Eleventh Circuit allowed an antitrust claim to proceed where the generic manufacturer had agreed never to enter the market, since such an agreement “excluded competition beyond ‘the scope of exclusion intended by the . . . patent.’” *Watson Pharm.*, 677 F.3d at 1311 (omission in original) (quoting *Andrx*, 421 F.3d at 1235).

³⁴ *Watson Pharm.*, 677 F.3d at 1310 (quoting *Schering-Plough*, 402 F.3d at 1066).

³⁵ *Id.* at 1315.

³⁶ *Id.* at 1312–15.

³⁷ *Actavis*, 133 S. Ct. at 2238.

³⁸ Justice Breyer was joined by Justices Kennedy, Ginsburg, Sotomayor, and Kagan. Justice Alito took no part in the consideration or decision of the case.

³⁹ *Actavis*, 133 S. Ct. at 2230.

⁴⁰ *Id.* at 2231.

tiff pays the defendant a sizeable sum despite the potential lack of liability, cautioned that this type of agreement could have significant anticompetitive effects.⁴¹

Noting that a prohibition on certain types of reverse-payment agreements might run contrary to the general policy encouraging parties to settle rather than to litigate, Justice Breyer offered five reasons why that policy should not govern this case: First, the settlement essentially allowed the developer to buy patent-like protection despite questions about the patent's validity, leading to adverse effects on competition.⁴² Second, the anticompetitive consequences of the settlement might not be justified by the benefits to the settling parties, suggesting that the parties intended the agreement as a mechanism for sharing monopolistic profits.⁴³ Third, reverse-payment agreements are generally associated with supracompetitive profits.⁴⁴ Fourth, antitrust actions might not be difficult to administer because the willingness of a developer to pay large sums to generic manufacturers "suggest[s] that the patentee has serious doubts about the patent's survival," thereby allowing an inference that the purpose of the agreement was to maintain an unjustified monopoly.⁴⁵ Finally, parties could still settle by reaching other arrangements, such as allowing the competing generic manufacturer to enter the market before the expiration of the patent (without making reverse payments).⁴⁶

Justice Breyer thus determined that the agreement should be subject to analysis according to both the monopolistic policies of patent law and the procompetitive policies of antitrust law.⁴⁷ Drawing on a series of cases that he asserted supported this contention, Justice Breyer claimed that the Court's jurisprudence had long embraced such balanced analysis.⁴⁸ In keeping with that assertion, Justice Breyer

⁴¹ *Id.*

⁴² *Id.* at 2234–35.

⁴³ *Id.* at 2235–36.

⁴⁴ *Id.* at 2236.

⁴⁵ *Id.* at 2236–37.

⁴⁶ *Id.* at 2237.

⁴⁷ *Id.* at 2231.

⁴⁸ *Id.* at 2231–33. The Court relied on *United States v. Line Material Co.*, 333 U.S. 287 (1948), *United States v. United States Gypsum Co.*, 333 U.S. 364 (1948), and *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), to establish that patentees were not immunized from antitrust law. See *Actavis*, 133 S. Ct. at 2231. According to the majority, in those cases, "rather than measure the length or amount of a restriction solely against the length of the patent's term or its earning potential . . . this Court answered the antitrust question by considering traditional antitrust factors." *Id.* The Court also pointed to several cases in which settlement agreements or licensing agreements were struck down as anticompetitive, including *United States v. Singer Manufacturing Co.*, 374 U.S. 174 (1963), *United States v. New Wrinkle, Inc.*, 342 U.S. 371 (1952), and *Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163 (1931). See *Actavis*, 133 S. Ct. at 2232.

rejected the FTC's suggestion that reverse payments should be per se illegal and instead ordered lower courts to adopt a rule-of-reason inquiry.⁴⁹

Chief Justice Roberts dissented.⁵⁰ Finding that the majority's decision had no basis in statute, the Chief Justice argued that the inquiry instead should have begun and ended with the question of whether the settlement granted monopoly power beyond that offered by the patent at issue.⁵¹ The Chief Justice cited extensive precedent to support his assertion that patent settlements were not subject to antitrust challenge.⁵² He then distinguished the cases cited by the majority by demonstrating that, in each case, the challenged action was outside the scope of the patent.⁵³ Furthermore, the Chief Justice noted that the question at issue — the validity of the patent — was clearly a matter of patent law and that the majority's reliance on antitrust principles was therefore inapposite.⁵⁴ The settlement agreement in question was clearly permissible if the patent was valid, and the parties came to a reasonable accommodation to settle the suit regarding the patent's validity rather than exposing themselves to the uncertainties of litigation.⁵⁵ Chief Justice Roberts also pointed out that, because validity of the patent would moot the antitrust suit, the generic manufacturers would be put into the “especially awkward position of being for the patent after being against it.”⁵⁶ The Chief Justice concluded by predicting that the uncertainty generated by the Court's hybrid approach would “weaken[] the protections afforded to innovators by patents, frustrate[] the public policy in favor of settling, and likely undermine[] the very policy it seeks to promote.”⁵⁷

⁴⁹ *Actavis*, 133 S. Ct. at 2237. A rule-of-reason analysis requires a balancing of the procompetitive and anticompetitive effects of an action. Although seemingly simple, this analysis has frequently resulted in a complex system of shifting burdens, with different courts applying the rule in different ways. Decisions follow some general guidelines, but substantial uncertainty persists. See Thomas C. Arthur, *A Workable Rule of Reason: A Less Ambitious Antitrust Role for the Federal Courts*, 68 ANTITRUST L.J. 337, 357–67 (2000).

⁵⁰ Chief Justice Roberts was joined by Justices Scalia and Thomas.

⁵¹ See *Actavis*, 133 S. Ct. at 2238 (Roberts, C.J., dissenting).

⁵² *Id.* (“A patent . . . is an exception to the general rule against monopolies.” (omission in original) (quoting *Walker Process*, 382 U.S. at 177) (internal quotation marks omitted)); *id.* (“[T]he precise terms of the grant define the limits of a patentee's monopoly and the area in which the patentee is freed from competition.” (alteration in original) (quoting *Line Material*, 333 U.S. at 300) (internal quotation marks omitted)); *id.* at 2239 (“It is only when . . . [the patentee] steps out of the scope of his patent rights' that he comes within the operation of the Sherman Act” (alteration and omission in original) (quoting *United States v. Gen. Elec. Co.*, 272 U.S. 476, 485 (1926))).

⁵³ *Id.* at 2240–41.

⁵⁴ *Id.* at 2240.

⁵⁵ *Id.* at 2244.

⁵⁶ *Id.* at 2243.

⁵⁷ *Id.* at 2247.

The current pharmaceutical settlement regime undoubtedly has its unsavory aspects, and the Court is hardly the first entity to attempt to solve these problems.⁵⁸ However, the Court has upset the existing framework with an alternative that will create uncertainty and instability. Because neither the antitrust nor the patent claims were inherently legally superior to the other and the Court lacks expertise in the economics of the pharmaceutical industry, the Court should have, as the dissent suggested, prioritized judicial administrability by protecting settlement agreements within the scope of the challenged patent.

Patent law and antitrust law have long existed in tension. Ordinarily, a deal under which a company with a product on the market paid another company to keep a competing product off the market for a period of time would be presumptively illegal under antitrust law.⁵⁹ It has long been accepted, however, that a valid patent creates a period of legal monopoly.⁶⁰ Several circuits therefore created a standard under which any agreement was permissible so long as it did not exceed the scope of the patent.⁶¹ To the extent that a deal might have anti-trust implications, the analysis was therefore straightforward: if the agreement was within the scope of the patent, then patent law controlled and the antitrust claim was dismissed; if the agreement was outside the scope of the patent, then patent law was inapplicable and ordinary antitrust principles applied.⁶² In addition to being easy for courts to apply, this analytical framework allowed pharmaceutical companies to reach settlement agreements instead of engaging in costly and uncertain litigation. At least one circuit, however, adopted a more restrictive rule that treated any pay-for-delay agreement as prima facie evidence of an antitrust violation.⁶³

⁵⁸ See, e.g., Preserve Access to Affordable Generics Act, S. 214, 113th Cong. (2013); Preserve Access to Affordable Generics Act, S. 27, 112th Cong. (2011); Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009); Press Release, Fed. Trade Comm'n, FTC Study: In FY 2012, Branded Drug Firms Significantly Increased the Use of Potential Pay-for-Delay Settlements to Keep Generic Competitors off the Market (Jan. 17, 2013), available at <http://www.ftc.gov/opa/2013/01/mmarpt.shtm> (quoting FTC Chairman Jon Leibowitz as noting that "[u]ntil this issue is resolved, we will all suffer the consequences of delayed generic entry").

⁵⁹ See *Actavis*, 133 S. Ct. at 2242 (Roberts, C.J., dissenting).

⁶⁰ See *id.* at 2240.

⁶¹ See, e.g., *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006) ("Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." (quoting *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 535 (E.D.N.Y. 2005)) (internal quotation marks omitted)); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003) ("We recognize [that] the patent exception to antitrust liability . . . is limited by the terms of the patent and the statutory rights granted the patentee."); see also *Actavis*, 133 S. Ct. at 2239 (Roberts, C.J., dissenting) (relying on this standard).

⁶² *Actavis*, 133 S. Ct. at 2242 (Roberts, C.J., dissenting).

⁶³ See *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012).

While the majority in *Actavis* correctly asserted that the “scope of the patent” test allowed litigants to protect potentially invalid patents or to pay noninfringing competitors to stay clear of the market, neither the majority nor Chief Justice Roberts’s dissent could conclusively resolve the patent-antitrust tension by appealing to precedent. Although the majority made a gesture toward precedent by asserting that previous cases had established that an antitrust inquiry could be applied to patent agreements, the dissent correctly distinguished the bulk of the precedent cited by Justice Breyer by showing that in each case, the Court had deemed the challenged action outside the scope of the patent. Similarly, the dissent could offer no prior decision of the Court that suggested that lower courts should not evaluate whether these agreements create an undue restraint on trade. An appeal to statute was likewise unavailing; the Hatch-Waxman Act, after all, was an act of compromise intended to strike an appropriate balance by providing stronger protections for the developers of legitimately novel drugs while incentivizing generic manufacturers to challenge weak patent claims. It does not clearly resolve the issues raised by the intersection of patent and antitrust.⁶⁴

In the absence of clear guidance from statute or precedent, both majority and dissent turned to policy arguments. The majority emphasized the procompetitive policy goals of antitrust law,⁶⁵ while the dissent emphasized the anticompetitive policy goals of patent law.⁶⁶ Since Congress has not mandated the superiority of either antitrust or patent, the Court should have focused on administrability. Justice Breyer’s opinion downplayed the administrative difficulties of a system in which courts will be asked to make subjective assessments of whether settlement agreements indicate patent weakness. The majority had no compelling answer to the dissent’s assertion that ease of administration and the general presumption in favor of settlements coun-

⁶⁴ See Linda P. Nussbaum & John D. Radice, *Where Do We Go Now? The Hatch-Waxman Act Twenty-Five Years Later: Successes, Failures, and Prescriptions for the Future*, 41 RUTGERS L.J. 229, 231 (2009). For the first decade and a half of the Hatch-Waxman regime, the system functioned largely as intended. See Hemphill & Lemley, *supra* note 4, at 954–55. The FTC interpreted the statute as allowing generic manufacturers to reap the benefits of their challenges only if they succeeded on the merits; this interpretation disincentivized pay-for-delay agreements, since the FTC would not allow such agreements to include the critical 180-day exclusivity period. See *id.* In 1998, the D.C. Circuit ruled that the FTC did not have the authority to require success on the merits. *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1076 (D.C. Cir. 1998). This ruling allowed first-filing generics to retain exclusivity despite settling the patent litigation, ushering in the era of pay-for-delay. See Gregory Dolin, *Reverse Settlements as Patent Invalidity Signals*, 24 HARV. J.L. & TECH. 281, 292–93 (2011).

⁶⁵ See *Actavis*, 133 S. Ct. at 2234–37.

⁶⁶ *Id.* at 2238 (Roberts, C.J., dissenting).

seled maintaining the status quo.⁶⁷ While the Court's emphasis on protecting consumers might be laudable, the Court's foray into policymaking will result in judicial uncertainty and may have unforeseen consequences in the market.

Rather than providing guidance regarding the scope of its decision, the Court left "to the lower courts the structuring of . . . rule-of-reason antitrust litigation."⁶⁸ Under a narrow reading of *Actavis*, the Court has only excised the "pay" portion of pay-for-delay. Pharmaceutical developers will no longer be able to offer cash payments to generic manufacturers in exchange for delayed entry into the market, but the incentives have not noticeably changed: developers and generic manufacturers will both still prefer settlement to litigation of the patent claims.⁶⁹ Other elements of the settlement system remain intact; de-

⁶⁷ Though the majority offered a five-part explanation for why ease of administration and the general judicial policy in favor of settlements should not have dictated a result in this case, only the last two elements of that explanation were directly relevant; the first three merely restated the risks and harms of anticompetitive behavior. *See id.* at 2234–37 (majority opinion). The Court responded to the ease-of-administration concern by simply dismissing the argument that a risk-averse holder of a valuable patent might be willing to make a substantial payment in order to avoid a very small risk of invalidation. *Id.* at 2236. Justice Breyer asserted that a large payment served as a signal that the patent holder was "likely seek[ing] to prevent the risk of competition," which in itself was an anticompetitive harm. *Id.* This analysis unfairly restricts the options available to a patent holder and pushes parties to the courts. Under the *Actavis* framework, a pharmaceutical developer who was 95% confident in its \$100 million patent could face antitrust scrutiny for agreeing to pay \$4 million to a generic manufacturer in exchange for the generic dropping a patent challenge. While the Court would consider this agreement a payment to prevent the risk of competition, it could more appropriately be understood as a prudent response to the risk inherent in all litigation. *Actavis* exposes pharmaceutical patent holders to treble-damage antitrust suits for making an otherwise economically rational decision. *See* Alan Morrison, *Commentary: Subjecting Reverse Payments in Patent Cases to Antitrust Scrutiny: Sounds Like a Good Idea, But Can It Work?*, SCOTUSBLOG (July 25, 2013, 10:23 AM), <http://www.scotusblog.com/?p=167756> (noting the difficulty in determining whether payments are large and unjustified). *But see* Michael Carrier, *Actavis and "Large and Unjustified" Payments*, SCOTUSBLOG (July 26, 2013, 4:09 PM), <http://www.scotusblog.com/2013/07/actavis-and-large-and-unjustified-payments> (arguing that factfinders will be able to distinguish between legitimate and illegitimate settlement agreements). The Court also asserted that settlements will continue. *See Actavis*, 133 S. Ct. at 2238. This claim discounts the possibility that lower courts will adopt a broader reading of *Actavis* under which almost all settlement agreements could be challenged.

⁶⁸ *Actavis*, 133 S. Ct. at 2238.

⁶⁹ *Cf.* Hemphill & Lemley, *supra* note 4, at 948 (noting that both generic and brand name manufacturers were incentivized to game the system). Generics are incentivized to settle because of the structure of the 180-day exclusivity period provided by the Hatch-Waxman Act and its successors. *Id.* at 948–49. Generic manufacturers derive a large portion of their profits from this six-month period in which they are the sole competition to the expensive brand-name drug because they are able to sell their products at a very slight markdown from the brand-name. *Id.* Once other generics enter the market, prices plummet and profits go down. It seems reasonable to suggest that generic manufacturers might actually prefer settling for early entry over winning a patent challenge, since the profits generated during the exclusivity period may very well be greater if the brand-name drug has already established itself in the marketplace. While brand-name manufacturers with a high risk tolerance and a high degree of confidence in their patents might be

velopers can still pay generics for services such as offering backup production capacity or promising to promote products. Indeed, one consequence of the Court's decision is that lower courts now must determine the actual value of such services and whether developers are overpaying generics to perform them. The Court's intended outcome, however, seems to be that the patentees will allow the generics earlier entry into the market in lieu of payments for delay. If the system functions exactly as the Court foresees, consumers will benefit as generic drugs are brought to market sooner.⁷⁰

Under a broad reading of *Actavis*, however, almost all settlement agreements between generics and developers could be subject to anti-trust challenge: a lower court could plausibly read the decision as indicating that any agreement by which the challenging generic obtained benefits that it otherwise would not have gained should be subject to antitrust evaluation. Since pharmaceutical developers' best defense against these antitrust challenges will be establishing the validity of the patent, they will have little incentive to settle the initial disputes with generic manufacturers. In addition to contravening the long-established judicial preference for settlement over litigation — and in addition to forcing developers to incur the costs of defending even strong patents — *Actavis* will create substantial uncertainty as courts determine how to interpret the decision.

The range of interpretations may hew to either extreme or may fall somewhere in between. For example, some courts might allow anti-trust challenges only to cash settlements, while other courts might scrutinize other quid pro quo deals. Even if every lower court determines that only large, unjustified payments are subject to challenge, there may be differences concerning how courts define the terms. One court might find that a \$10 million payment is quite large, while another might determine that it is relatively modest in relation to a drug's expected profits. As the post-*Actavis* jurisprudence evolves in the lower courts, developers will face uncertainty from subjective determinations and inconsistency across courts.

The Court's decision in *Actavis* upsets the established framework for pharmaceutical settlements without providing a system that is certain to maintain the balance between antitrust and patent law. Because the law did not mandate this decision, the Court should have prioritized judicial administrability by protecting settlement agreements within the scope of the relevant patent.

more willing to litigate under the *Actavis* regime, those with a lower risk tolerance or a lower degree of confidence will still wish to settle rather than to engage in the uncertain litigation process.

⁷⁰ If the profits lost by developers as a result of the shorter exclusivity period are offset by the profits gained by the developers as a result of not having to pay generic manufacturers, then the market price of drugs should stay relatively stable.