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The Supreme Court's June 2013 decision in *FTC v. Actavis, Inc.*[1] raised as many new questions as it answered regarding the application of antitrust law to drug patent settlement agreements. The Court steered a middle course on the issue of so-called "reverse payment" settlements, concluding that such settlements *might* violate federal antitrust law but providing little guidance regarding when violations should be found. The Court concluded that reverse payment settlements should be subject to the "rule of reason," rejecting both the FTC's argument that they should be deemed presumptively anticompetitive and the much more restrictive "scope of the patent" test espoused by the lower court.[2]

Further complicating the issue is the possible application of state antitrust law. Private plaintiffs who challenge reverse payment settlements often allege that the settlements violate state antitrust law as well as federal antitrust law.[3] Defendants who successfully defend against federal antitrust claims may still find themselves facing claims that their patent settlements nonetheless violated state law. A key issue with

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* Chief Counsel, Washington Legal Foundation.

1. 133 S. Ct. 2333 (2013).

2. *Actavis*, 133 S. Ct. at 2237–38.

3. *See, e.g.*, Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (Fed. Cir. 2010); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2005) ("The district court . . . . dismissed the plaintiffs' state-law claims, which had alleged violations of the antitrust laws of seventeen states and violations of consumer protection and unfair competition laws of twenty-one states, because those claims were based on the same allegations as the plaintiffs' federal antitrust claims." (internal citation omitted)); *In re* Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003); *In re* Cipro Cases I & II, 134 Cal. Rptr. 3d 165, 174 (Cal. Ct. App. 2011), *rev. granted*, 269 P.3d 653 (Cal. 2012).

respect to state claims will have to be addressed by the courts: to what extent does federal law preempt state antitrust law in this area? In particular, are states permitted to impose antitrust liability on parties to reverse payment patent settlements for conduct not deemed actionable under federal law?

This paper concludes that state antitrust liability can be imposed on parties to patent settlements so long as the state action "parallels" federal antitrust law. On the other hand, state law is preempted to the extent that it seeks to impose antitrust liability for conduct not deemed actionable under federal law; under such circumstances, state-law liability would be impliedly preempted because it would stand as an obstacle to accomplishing the purposes of federal patent law. The scope of preemption likely would include any effort by states to apply a stricter standard of review to reverse payment patent settlements—either a "quick look" review accompanied by a presumption of illegality, or a declaration that such settlements are "per se" illegal.

Part I of this paper summarizes federal preemption law as it has been applied to state antitrust actions. It explains that the U.S. Supreme Court has never interpreted federal antitrust law as imposing a limit on states' authority to regulate business practices deemed by states to have anticompetitive effects. Nonetheless, federal courts have not hesitated to rule that state antitrust law is preempted by federal law when they determine that state law comes into conflict with some other federal statute. In this instance, the relevant "other federal statute" is federal patent law.

Part II examines the Supreme Court's *Actavis* decision and explains that *Actavis* attempted to balance the conflicting demands of federal antitrust law and patent law. The decision was based on what the Court deemed the appropriate balance between those conflicting demands, and the paper concludes that states may not adopt policies that would conflict with the balance arrived at by the Court.

Parts III and IV examine the extent to which *Activis* and other Supreme Court decisions should be deemed to preempt state antitrust law challenges to reverse payment patent settlements. They conclude that state antitrust law should be deemed preempted to the extent that it attempts to impose liability under state law in circumstances under which federal law would not permit imposition of antitrust liability. The paper recognizes, however, that state antitrust claims of this

sort are likely to become increasingly common and that defendants may not always prevail in their efforts to convince state courts to rule that expansive state law claims are preempted. Moreover, even when state courts are purporting to do no more than enforce state antitrust law that merely "parallels" federal antitrust law, defendants may nonetheless encounter greater difficulty (in comparison to federal court proceedings) in convincing a state-court fact-finder that settlement of their patent dispute had pro-competitive effects.

I. STATE ANTITRUST LAW

Congress has passed a series of laws over the past 125 years designed to prevent businesses from engaging in anticompetitive conduct that results in higher prices for consumers. Most prominently, it adopted the Sherman Act in 1890.[4] Section 1 of the Sherman Act prohibits "[e]very contract, combination in the form or trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States."[5] Among the types of agreements deemed to constitute per se violations of section 1 are agreements among competitors to limit output.[6]

Many states have also adopted antitrust statutes. While those laws tend to be similar to federal law, their language is not identical, and state courts routinely interpret state antitrust laws in ways that diverge sharply from federal law.[7] For example, California's antitrust statute, the Cartwright Act,[8] diverges in a number of respects from federal antitrust law. The California Supreme Court recently cautioned, "[i]nterpretations of federal antitrust law are at most

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4. Sherman Act, ch. 647, 26 Stat. 209 (1890) (codified as amended at 15 U.S.C. §§ 1–7 (2012)).

5. 15 U.S.C. § 1 (2012).

6. *See, e.g.*, Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 877, 893 (2007) ("A horizontal cartel among competing manufacturers or competing retailers that decreases output or reduces competition in order to increase price is, and ought to be, *per se* unlawful.").

7. *Cf.* Herbert Hovenkamp, *State Antitrust in the Federal Scheme*, 58 IND. L.J. 375, 377 n.10 (1983) ("As a general matter, state antitrust laws are substantively similar to federal antitrust law, and many state courts have held that case law interpreting the federal statutes is fully applicable to corresponding state statutes. . . . [H]owever, as a result either of statutory language or judicial interpretation, some state antitrust laws are now broader than federal law." (internal citations omitted)).

8. CAL. BUS. & PROF. CODE §§ 16700–16770 (West 2008).

instructive, not conclusive, when construing the Cartwright Act . . . ."[9]

The U.S. Supreme Court has rejected claims that state antitrust law is preempted whenever it diverges from federal antitrust law. For example, the Court permitted the Attorneys General of Alabama, Arizona, California, and Minnesota to file antitrust claims under their respective state laws against a group of cement producers even though those state governments, because they did not purchase cement directly from the producers but rather purchased only through intermediaries, would not have been proper plaintiffs under federal antitrust law.[10] Under federal law, when producers conspire to fix prices, only direct purchasers, and not subsequent indirect purchasers, are permitted to sue to recover losses incurred as a result of the conspiracy.[11] In contrast, antitrust laws from the four states permitted recovery by indirect purchasers.[12] The Supreme Court rejected the defendant cement producers' assertion that federal antitrust law was intended to serve as a ceiling on businesses' liability for engaging in anticompetitive conduct.[13] It stated, "Congress intended the federal antitrust laws to supplement, not displace, state antitrust remedies. And on several prior occasions, the Court has recognized that the federal antitrust laws do not pre-empt state law."[14]

On the other hand, state antitrust laws—like all state laws—are subject to the restrictions imposed by the Supremacy Clause of the U.S. Constitution,[15] and are impliedly preempted

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9. Aryeh v. Canon Bus. Solutions, Inc., 292 P.3d 871, 877 (Cal. 2013).

10. California v. ARC Am. Corp., 490 U.S. 93 (1989); *see id.* at 101–02 ("There is no claim that the federal antitrust laws expressly pre-empt state laws permitting indirect purchaser recovery . . . . Congress intended the federal antitrust laws to supplement, not displace, state antitrust remedies.").

11. Ill. Brick Co. v. Illinois, 431 U.S. 720, 730–32 (1977); *id.* at 746 ("[T]he legislative purpose in creating a group of private attorneys general to enforce the antitrust laws . . . is better served by holding direct purchasers to be injured to the full extent of the overcharge paid by them than by attempting to apportion the overcharge among all that may have absorbed a part of it." (internal citations and quotation marks omitted)).

12. *ARC*, 490 U.S. at 98.

13. *Cf. id.* at 105 ("Ordinarily, state causes of action are not pre-empted solely because they impose liability over and above that authorized by federal law, and no clear purpose of Congress indicates that we should decide otherwise in this case." (citation omitted)).

14. *Id.* at 102 (citation omitted).

15. U.S. CONST. art. VI, cl. 2.

to the extent that they conflict with federal law.[16] Such a conflict arises when "compliance with both federal and state regulations is a physical impossibility,"[17] or when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[18] On a number of occasions, the Supreme Court has concluded that state antitrust law is preempted because it conflicts with a federal statute other than federal antitrust law.[19]

The Court has been particularly quick to find preemption when state antitrust law has an impact on labor law, an area in which federal law is pervasive.[20] Indeed, on at least one occasion, the Court found that a claim arising under *state* antitrust law was preempted by federal labor law even though the Court concluded that the conduct that gave rise to the state claim could proceed as a claim under *federal* antitrust law.[21] The Court explained that "Congress and this Court have carefully tailored the antitrust statutes to avoid conflict with the labor policy favoring lawful employee organization, not only by delineating exemptions from antitrust coverage but also by adjusting the scope of the antitrust remedies themselves."[22] The Court said that state antitrust laws "generally have not been subjected to this process of accommodation" and thus that "[t]he use of state antitrust law . . . [must] be pre-empted because it creates a substantial risk of conflict with policies central to federal labor law."[23]

Accordingly, in any challenge to a "reverse payment" patent settlement arising under state antitrust law, a court will likely be required to address whether the claim conflicts with the "balance" between federal antitrust law and federal patent law established by the Supreme Court's *Actavis*

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16. *See, e.g.*, Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2473 (2013) ("Even in the absence of an express pre-emption provision, the Court has found state law to be impliedly pre-empted where it is 'impossible for a private party to comply with both state and federal requirements.'").

17. Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142–43 (1963).

18. Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

19. *See, e.g.*, Connell Constr. Co. v. Plumbers & Steamfitters Local Union No. 100, 421 U.S. 616 (1975); Local 24 of Int'l Bhd. of Teamsters v. Oliver, 358 U.S. 283 (1959).

20. *See, e.g.*, *Local 24*, 358 U.S. at 296.

21. *Connell Constr. Co.*, 421 U.S. at 635–36.

22. *Id.* at 636.

23. *Id.* at 635–36.

decision. If such state-law antitrust claims stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress in adopting the patent laws, it will be preempted by federal law.

II. "REVERSE PAYMENT" PATENT SETTLEMENTS

When parties to litigation enter into a settlement, one would normally expect that any cash payments would flow from the defendant to the plaintiff. The defendant pays cash in return for something from the plaintiff: the abandonment of a legal claim. The normal expectations have been reversed in the context of litigation involving prescription drug patents, however, as the result of financial incentives created by the Hatch-Waxman Act,[24] a federal statute adopted in 1984. Hatch-Waxman was designed to ensure that generic versions of prescription drugs enter the market more quickly, thereby driving down drug prices.[25] The Act includes a provision that permits generic companies, by announcing plans to market a drug before expiration of the drug's patent, to essentially force the patent holder to immediately file a patent infringement suit.[26] That provision sets drug patent litigation apart from all other types of patent litigation. It allows generics to challenge the validity of a drug patent in a virtually risk-free manner—because they can induce a patent lawsuit without actually selling an infringing product,[27] generics can place a patent's

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24. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 16, 21, 28, and 35 U.S.C.).

25. *See, e.g.*, Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1058 n.2 (11th Cir. 2005) ("The purpose of the Hatch-Waxman Act was threefold: (1) to reduce the average price paid by consumers; (2) preserve the technologies pioneered by the brand-name pharmaceutical companies; and (3) create an abbreviated new drug application ('ANDA') to bring generic drugs to the market.").

26. *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1566 (2006) ("Submitting an ANDA containing such [a Paragraph IV Certification] is an act of infringement that often prompts the innovator to file a patent suit." (footnote omitted); *see also* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012) (requiring a generic drug company planning to market a generic version of a patented drug to certify to the FDA, as one of four options, that the patentee's patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted").

27. *See* Gregory Dolin, *Reverse Settlements as Patent Invalidity Signals*, 24 HARV. J.L. & TECH. 281, 293–94 (2011) ("[U]nlike usual patent litigation where the dispute touches on products that are already on or about to enter

validity at issue without the risk of incurring the potentially bankrupting damage awards normally associated with patent litigation.[28]

While the cost of litigation is about the only loss that a generic company is likely to suffer if it loses a drug patent infringement lawsuit, the stakes are much higher for the typical prescription drug patent holder. It likely spent hundreds of millions of dollars to obtain FDA approval to market its product.[29] It can hope to recoup those costs only if it can maintain the validity of its patent and thereby prevent competition from generic manufacturers.[30] For a typical brand-name prescription drug manufacturer, its patents on the drugs it produces are far and away its most valuable assets. A brand-name drug manufacturer often stands to lose billions of dollars in future revenues if one of its key drug patents is declared invalid.[31] In light of the dynamics created by the Hatch-Waxman Act, it is hardly surprising that generic companies—even though they are the defendants in drug patent infringement litigation—are in a position to demand cash or other valuable assets in return for agreeing to settlement of the patent litigation.

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the market, Hatch-Waxman litigation occurs prior to the generic drug actually entering the market.").

28. *See id.* Individuals generally lack legal standing to challenge the validity of patents issued to another. Such challenges only come about as a defense to an infringement lawsuit filed by the patent holder, and infringement suits (outside the context of prescription drug patents) may be filed only after the defendant has started to sell an infringing product. Because damages in an infringement suit are awarded on the basis of losses suffered by the patent holder and because such damages can often be many times larger than the profits earned by the defendant from his infringing sales, the loss of a significant patent lawsuit can easily drive the infringer into bankruptcy.

29. *See* Hemphill, *supra* note 26, at 1564–65 ("[Demonstrating that a drug is safe and effective as part of a so-called New Drug Application (NDA) is a lengthy, expensive process, consuming years and many millions of dollars to conduct the necessary clinical trials." (footnote omitted)).

30. *See id.* at 1562–63.

31. *See id.* at 1557 ("If the generic firm wins in litigation, either by establishing that the patent is invalid or not infringed by the generic firm's competing product, the generic firm wins the means to enter the market prior to scheduled expiration. Successful pre-expiration challenges reallocate billions of dollars from producers to consumers.").

III. *ACTAVIS*: AN ANTITRUST CHALLENGE TO "REVERSE PAYMENT" SETTLEMENTS

The Federal Trade Commission (FTC) has long complained about the allegedly anticompetitive effects of "reverse payment" patent settlements—settlements whose terms include a cash payment from the drug patent holder to the alleged infringer.[32] The FTC contends that by making such payments, patent holders are in effect paying potential competitors not to compete, thereby restricting supply and driving up prices.[33] Drug companies have responded that such settlements cannot have an anticompetitive effect so long as the settlement does not prohibit any competition that was not already barred under the terms of the patent.[34] They argue that because litigation is always a drain on productivity, settlements of patent disputes ought to be encouraged for their pro-competitive effects[35] and that existing patents ought to be presumed valid.[36]

Lower federal courts have struggled for more than a decade to craft a coherent theory for addressing antitrust challenges to reverse payment settlements.[37] On the one hand, there is reason for concern about the competitive consequences of settlements that include substantial payments from the patent holder to the alleged infringer. Very large payments may be an indication that the settling parties recognized that the patent was particularly vulnerable to invalidation,[38] and thus that competition would have begun much sooner had the infringement suit been permitted to proceed to a trial, at which

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32. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013) ("Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars. Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a 'reverse payment' settlement agreement.").

33. *See* Brief for the Petitioner at 15–16, FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 267027.

34. *See* Brief for Respondent Actavis, Inc. at 47, FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 662705.

35. *Id.* at 51.

36. *Id.* at 18–19.

37. *See, e.g.*, Carl W. Hittinger & Lesli C. Esposito, In re K-Dur Antitrust Litigation*: The Third Circuit's Controversial Pay-for-Delay Antitrust Decision Splits with Other Circuit Courts*, 58 VILL. L. REV. 103, 107–15 (2013).

38. *See, e.g.*, Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 ANTITRUST BULL. 491, 533–34 (2002).

the patent almost surely would have been declared invalid. Viewed in that light, payments from the patent holder to the alleged infringer can be seen as a device for sharing monopoly rents made possible by the alleged infringer's agreement not to compete.[39]

On the other hand, a patent holder has a legal right to a monopoly on the sale of its patented product. It thus is hard to fault the patent holder for taking steps to enforce that right, even if those steps include making payments to litigation opponents where economic incentives created by the Hatch-Waxman Act essentially require such payments as the price of settling litigation.[40]

One potential solution to this dilemma is to instruct trial courts to examine the strength of the underlying patent.[41] Under that approach, a reverse payment patent settlement would be deemed anticompetitive, and thus in violation of federal antitrust law, if and only if the court determined that the patent was weak and likely would have been declared invalid had the patent infringement suit been allowed to go to trial. But advocates on both sides of the issue have resisted that approach because it would require overly complex trials. District courts conducting an antitrust trial would be required to retry the previously-settled patent dispute, hearing voluminous evidence regarding patent validity.[42] To avoid that

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39. *See, e.g.*, Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1749–51 (2003).

40. *See, e.g.*, *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 209–10 (2d Cir. 2006), *cert. denied*, 551 U.S. 144 (2007).

41. *See, e.g.*, Brief for the United States as Amicus Curiae at 12, Joblove v. Barr Labs., Inc, 551 U.S. 1144 (2007) (No. 06-830), 2007 WL 1511527 ("The dissenting opinion below correctly suggested that a court reviewing an antitrust challenge to a settlement of a patent infringement claim that includes a reverse payment should apply the rule of reason—and that, in doing so, a court should consider 'the strength of the patent as it appeared at the time at which the parties settled.'").

42. *Cf.* Dolin, *supra* note 27, at 284–85 ("[T]he antitrust approach may undermine patent law uniformity, as presumably whatever findings a district court would make on antitrust liability could—and would—be appealed. The appeals, like any other appeal on issues of antitrust law, would likely be heard by the regional circuit courts of appeals, which would then be tasked with evaluating the validity and strength of the patents underlying the antitrust litigation. This could put the regional circuits on a collision course with the U.S. Court of Appeals for the Federal Circuit, which is a specialist court with exclusive jurisdiction over patent disputes. Such an outcome would put complicated technical patent questions in the hands of non-specialist judges, and would run directly contrary to the congressional desire for uniformity of patent law throughout the country." (footnotes omitted)).

result, the FTC has argued that reverse payment settlements should be deemed per se antitrust violations,[43] reasoning that patent holders should be required to agree to an earlier onset of generic competition in lieu of making cash payments to the alleged infringers.

Prior to 2012, the FTC and private plaintiffs had lost their challenges to reverse payment drug patent settlements. The Second, Eleventh, and Federal Circuits each adopted the so-called "scope of the patent" test, which holds that agreements that do not extend beyond the exclusionary effect of a patent do not injure lawful competition unless the patent was procured by fraud or the infringement claim was objectively baseless.[44] Under this standard, the patent holder's right to exclude infringing competition is fully respected unless the antitrust plaintiff can demonstrate that the patent had no exclusionary effect at all.[45]

In 2012, the Third Circuit created a split among the federal appeals courts by adopting the FTC's position. It held that reverse payment settlements are prima facie evidence of an unreasonable restraint of trade, and that the settling parties can rebut that presumption only if they are able to demonstrate, during a "quick look" analysis, that the settlement actually has pro-competitive effects.[46] The Third Circuit added that it agreed with the FTC that

> there is no need to consider the merits of the underlying patent suit because absent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement

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43. By the time *Actavis* reached the Supreme Court, the FTC had modified its position. Instead of seeking a per se rule, the FTC argued that reverse payment settlements should be merely presumptively unlawful, and that courts should conduct a "quick look" review during which the settling parties would bear the burden of demonstrating that their settlement was, in fact, pro-competitive. Brief for the Petitioner at 33–40, FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 267027.

44. *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied*, 557 U.S. 920 (2009); *In re Tamoxifen*, 466 F.3d at 213; Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 584 U.S. 919 (2006).

45. *See, e.g.*, *Schering-Plough*, 402 F.3d at 1066 ("[T]he proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects.").

46. *In re* K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012), *vacated*, 133 S. Ct. 2849 (2013).

> by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.[47]

Actavis resolved that circuit split.

The *Actavis* litigation was an FTC challenge to a reverse payment settlement of patent infringement litigation involving a brand-name drug called AndroGel.[48] Under the terms of the settlement, the alleged infringers (several generic drug manufacturers) agreed not to market their generic versions of AndroGel until August 2015, sixty-five months *before* the AndroGel patent was scheduled to expire.[49] The settlement also required the patent holder to pay many millions of dollars to the generic manufacturers; it stated that the payments were in return for other services to be performed by the generics for the patent holder.[50] The FTC filed a complaint against all settling parties under federal antitrust law, contending that "the true point of the payments was to compensate the generics for agreeing not to compete against AndroGel until 2015."[51] Applying its previously adopted "scope of the patent" test, the Eleventh Circuit affirmed the district court's dismissal of the FTC's complaint.[52] It reasoned that the settlement could not be deemed to have anticompetitive effects because it permitted generic competition sixty-five months before the underlying patent was scheduled to expire.[53] The Supreme Court granted review to resolve the conflict between the Third Circuit on the one hand and the Second, Eleventh, and Federal Circuits on the other hand.

In its June 2013 decision, the Supreme Court rejected both the "scope of the patent" test and the Third Circuit's "presumption of unreasonable restraint" test.[54] The Court declined to adopt any bright line test and instead directed lower courts to analyze the potential anticompetitive effects of reverse payment settlements under a traditional "rule of reason" analysis.[55] The Court repeatedly emphasized that courts must "balance" the competing interests of federal

47. *Id.* (internal quotation marks omitted).
48. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2229 (2013).
49. *Id.*
50. *Id.*
51. *Id.*
52. FTC v. Watson Pharm., Inc., 677 F.3d 1298 (11th Cir. 2012), *rev'd sub nom.* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013).
53. *Actavis*, 133 S. Ct. at 2227, 2229.
54. *Id.* at 2237–38.
55. *Id.*

antitrust and patent law, explaining that "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent."[56]

The Court acknowledged the legitimacy of the concerns that had led the Eleventh Circuit to adopt the "scope of the patent" test: the desirability of promoting settlements and the "fear that antitrust scrutiny of a reverse payment agreement would require the parties to litigate the validity of the patent in order to demonstrate what would have happened to competition in the absence of the settlement" and would "prove time consuming, complex, and expensive."[57] The Court nonetheless held that other considerations led it "to conclude that the FTC should have been given the opportunity to prove its antitrust claim."[58] Chief among those considerations was the Court's conclusion that settlements have the "potential for genuine adverse effects on competition,"[59] particularly when reverse payments are so large that they cannot be explained as an amount necessary to bring about a settlement.[60] The Court added that a plaintiff should not necessarily be required to demonstrate the weakness of the underlying patent in order to establish a prima facie case of antitrust unlawfulness, stating that "[a]n *unexplained* large reverse payment itself would normally suggest that the patentee had serious doubts about the patent's survival."[61]

In rejecting the FTC's argument that reverse payment settlements should be deemed "presumptively unlawful" and should proceed via a "quick look" approach, the Court explained:

> [A]bandonment of the "rule of reason" in favor of presumptive rules (or a "quick-look" approach) is appropriate only where "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on consumers and markets." We do not believe that reverse

56. *Id.* at 2231.
57. *Id.* at 2234.
58. *Id.*
59. *Id.* (quoting FTC v. Ind. Fed'n of Dentists, 476 US. 447, 460–61 (1986)).
60. *Id.* at 2234–35.
61. *Id.* at 2236 (emphasis added).

> payment settlements, in the context we here discuss, meet this criterion.[62]

Remanding the case to the Eleventh Circuit for further consideration, the Court said that it would "leave to the lower courts the structuring of the present rule-of-reason litigation."[63]

IV. WHAT DID *ACTAVIS* DECIDE?

Before determining the extent to which state antitrust regulation of reverse payment settlements is preempted by federal law, one must first determine what was actually decided by *Actavis*. While there is disagreement regarding which side actually won the case, all agree that the decision left a considerable number of issues undecided.

The Court explicitly rejected the Eleventh Circuit's "near-automatic antitrust immunity to reverse payment settlements" and the FTC's "presumptively unlawful" approach,[64] but provided relatively vague guidance for determining which such settlements violate federal antitrust laws and which do not. The Court said that "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival," and that the existence of such serious doubts "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 . . . ."[65] But those sentences raise more questions than they answer; they do not explain how a trial court is to determine whether the reverse payment is "unexplained" or "large" or when the "normal" inference from an "unexplained large reverse payment" might not be appropriate. The Court punted those issues to trial courts with instructions to do their best in applying a "rule of reason" analysis.[66] Moreover, while the Court determined that a plaintiff challenging a reverse payment settlement can establish a prima facie case without establishing that the patent was weak and would likely have been invalidated had

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62. *Id.* at 2237 (citations omitted) (quoting Cal. Dental Ass'n v. FTC, 526 U.S. 756, 770 (1999) (Breyer, J., concurring in part and dissenting in part)).

63. *Id.* at 2238. In light of its *Actavis* decision, the Court subsequently vacated and remanded the Third Circuit's *In re K-Dur* decision. Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co., Inc., 133 S. Ct. 2849 (2013).

64. *Actavis*, 133 S. Ct. at 2237.

65. *Id.* at 2236.

66. *Id*. at 2237–38.

the infringement suit gone to trial,[67] it did not determine whether trial courts may impose any limitations on defendants' rights to make the opposite showing: that the patent almost surely would have been upheld if the infringement suit had gone to trial and thus that the reverse payment settlement could not possibly have had any anticompetitive effects.

The Court did not even determine whether a reverse payment can ever be actionable when it takes the form of something other than cash. Use of the word "payment" at least *suggests* that the Court did not intend to address transfers of value other than cash, but the FTC has already rejected that interpretation and is attempting to use *Actavis* to challenge patent litigation settlements in which the value transferred to the infringing party consisted of an exclusive license to market a generic version of the drug during the first 180 days following expiration of the patent.[68] Of course, as Seventh Circuit Judge Richard Posner has pointed out, "*any* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements."[69]

The *Actavis* Court did make clear, however, that a license permitting an alleged infringer to bring its product to market prior to expiration of the patent cannot be classified as an unlawful reverse payment.[70] Suppose that a patent is not scheduled to expire for another ten years and that the parties reach a settlement whereby the alleged infringer agrees not to compete for the first seven years in return for an exclusive license to market its product during the final three years. Arguably, the alleged infringer has received something of considerable value (a three-year exclusive license) in return for agreeing not to compete for seven years. The Court nonetheless indicated that such agreements not to compete are not actionable under federal antitrust law[71]—perhaps because the

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67. *Id.* at 2236.

68. *See, e.g.*, Federal Trade Commission Brief as *Amicus Curiae* at 15–17, *In re* Effexor XR Antitrust Litig., No. 3:11-cv-05479 (D.N.J. Aug. 14, 2013).

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

70. *Actavis*, 133 S. Ct. at 2237.

71. *Id.* (stating that parties to drug patent litigation may, as in other industries, "settle in other ways [than making large cash reverse payments], for example, by allowing the generic manufacturer to enter the patentee's

exclusive license increases competition and thus benefits not only the alleged infringer but also consumers, even though the agreement not to compete arguably harms consumers.

Moreover, the Court's repeated use of the word "balance" and the phrase "accommodate patent and antitrust policies"[72] made clear that any "rule of reason" analysis undertaken by a district court must seek to balance the competing interests of federal antitrust law (to promote competition) and the federal patent law (to provide monopoly profits to the developers of new and useful products and thereby encourage development of more such products in the future).

Those holdings suggest some limits on the extent to which states should be permitted to impose antitrust liability on companies that enter into reverse payment drug patent settlements. In particular, any state-law liability is preempted to the extent that it would upset the balance between federal antitrust law and patent law established by *Actavis* because such liability would "stand[ ] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[73]

V. *ACTAVIS*'S PREEMPTIVE EFFECT

Application of state antitrust law to reverse payment settlements is not merely a hypothetical possibility. There are a fair number of pending lawsuits that challenge reverse payment settlements on state-law grounds. The California Supreme Court has agreed to review one such suit.[74] In seeking affirmance of the appeals court's dismissal of the suit, the

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market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point").

72. *See, e.g.*, *id.* at 2231, 2233.

73. Hines v. Davidowitz*,* 312 U.S. 52, 67 (1941).

74. *In re* Cipro Cases I & II, 269 P.3d 653 (Cal. 2012). The California Supreme Court held the case in abeyance while the U.S. Supreme Court was considering *Actavis*. It is reviewing a California Court of Appeals decision that invoked the "scope of the patent" test to dismiss the plaintiffs' claims that a reverse payment settlement violated state antitrust law. *In re* Cipro Cases I & II, 134 Cal. Rptr. 3d 165 (Cal. Ct. App. 2011), *rev. granted*, 269 P.3d 653 (Cal. 2012). The reverse payment settlement being challenged in *In re Cipro Cases I and II* was the subject of an unsuccessful challenge in the Second Circuit under federal antitrust law. *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 604 F.3d 98 (2d Cir. 2010).

defendants argue inter alia that the suit is preempted by federal law.[75]

As noted above, there is precedent for a finding that state antitrust law is preempted to the extent that it conflicts with the policy underlying a federal statute.[76] Moreover, in the context of patent law, federal courts have not hesitated to preempt state laws that the courts deem to stand as an obstacle to accomplishing Congress's objectives (i.e., encouraging efforts to develop new and useful products).[77] To the extent that any portions of *Actavis*'s holding can be deemed to reflect the Court's perception of Congress's new-product-development objectives, a state law is preempted if it is inconsistent with that holding and seeks to impose a greater degree of antitrust liability on the parties to a reverse payment settlement.

Actavis's treatment of settlements involving a compromise entry date appears to meet that description. *Actavis* held that federal antitrust liability could not arise from a settlement in which the generic manufacturer agrees not compete for a number of years and in return is rewarded with an exclusive license to market its product several years in advance of the patent's expiration date.[78] Accordingly, states are not permitted to impose antitrust liability under similar circumstances because doing so would upset the balance that, according to *Actavis*, Congress sought to achieve between antitrust and patent law.

Other issues left open by *Actavis* are likely to be answered in the years ahead. For example, the Supreme Court did not specify whether noncash benefits received by a generic manufacturer in connection with a patent settlement can ever serve as the basis for federal antitrust liability. If the Supreme Court eventually answers that question by stating: "No, federal

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75. *See, e.g.*, Answer Brief of Respondent Bayer Corp. at 41–47, *In re* Cipro Cases I & II, No. S198616 (Cal. May 30, 2012), 2012 WL 2379475.

76. *See, e.g.*, Local 24 of Int'l Bhd. of Teamsters v. Oliver, 358 U.S. 283 (1959); *supra* notes 19–23 and accompanying text.

77. *See, e.g.*, Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1372, 1374 (Fed. Cir. 2007) (finding that District of Columbia law prohibiting sale of patented drugs at "an excessive price" was impliedly preempted by federal patent law because it interfered with "Congress's intention to provide . . . pharmaceutical patent holders with the pecuniary reward that follows from the right to exclude granted by a patent").

78. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2237 (2013); *see supra* notes 71–72 and accompanying text.

antitrust law will not examine settlement benefits other than cash that flow to the infringing party," then it is likely that state antitrust law would be required to conform to that rule. The potential grounds for such a ruling (a desire both to promote settlement of patent disputes and to uphold reliance interests in existing patents) are based largely on values embedded in federal patent law.

There is little reason to believe, however, that the Court would prevent application of state antitrust law to patent settlement agreements where state law is fully consistent with federal antitrust law. Even in areas subject to extensive federal regulation, the Supreme Court has upheld the authority of states to engage in parallel regulation that is not inconsistent with the federal regulation.[79] Unless the Court were to determine, as in *Connell*,[80] that states could not be trusted to properly accommodate the objectives of the federal statute at issue (here, federal patent law), there is no reason to conclude that Congress would not have wanted states to be permitted to police the same sorts of anticompetitive conduct that is policed by federal antitrust law. Moreover, states are likely free to impose greater penalties on the proscribed conduct than is available under federal law. As the Court explained in *California v. ARC America Corp.*, state antitrust law is not required to adhere to the same set of sanctions imposed by federal antitrust law.[81]

It seems reasonably clear, however, that *Actavis* prohibits states from adopting the procedural devices rejected by the U.S. Supreme Court—either a per se condemnation of reverse payment settlements or a presumption of illegality accompanied by "quick look" review. The Supreme Court rejected those approaches because it determined that in many cases there might well be pro-competitive economic justifications for reverse payment settlements and that presuming their illegality could result in the suppression of economically useful conduct.[82] State antitrust laws that adopted the FTC's proposed presumption of illegality would be subject to similar criticism, and thus would likely be impliedly

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79. *See, e.g.*, Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008) (authorizing states to impose regulations on medical devices that precisely "parallel" federal regulations).

80. *See supra* notes 21–23 and accompanying text.

81. 490 U.S. 93, 102 (1989).

82. *Actavis*, 133 S. Ct. at 2237.

preempted as inconsistent with the careful balance between antitrust and patent law established by *Actavis*.

CONCLUSION

Because *Actavis* left so many questions unanswered regarding the application of federal antitrust law to patent settlement agreements, the extent to which federal law preempts the application of state antitrust law to such agreements remains similarly unsettled. One can be reasonably confident that if private plaintiffs become dissatisfied with the results of pending litigation under federal antitrust law, they will turn with increasing frequency to state antitrust law as an alternative remedy. Even if state law ends up doing no more than "parallel" federal antitrust law, defendants are likely to incur substantial litigation costs fending off such state claims in the years to come.