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Implications of *FTC v. Actavis*: A Reasonable Approach to Evaluating Reverse Payment Settlements

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The Court's opinion in *FTC v. Actavis, Inc.*[1] resolves the important threshold question of the appropriate legal lens through which to evaluate patent settlements where consideration flows from an innovator drug company to its generic challenger.[2] The Court rejected both the "presumption of illegality" advocated by the FTC and the so-called "scope of the patent" test favored by the drug manufacturer defendants, holding instead that agreements should be analyzed under the rule of reason.[3] Thus, reverse payment patent settlements will be evaluated on a case by case basis, considering factors including "[the payment's] size, its scale in relation to the payor's anticipated future litigation costs, its independence

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1. 133 S. Ct. 2223 (2013).

2. Settlements where the innovator drug company provides money or something else of value to the generic company have been referred to by various names, e.g., "reverse payments," "pay-for-delay," "exclusion payments." The terms "pay-for-delay" and "exclusion payments" mischaracterize settlements that have brought generic products to market months or years before patent expiration. Likewise, the term "reverse payment" is imprecise to the extent it implies that these settlements somehow stand apart from the norm, as consideration flowing from the innovator to the alleged infringer is a typical dynamic in settlements. *See* Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J.) ("[*A*]*ny* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement."). Yet, the Court adopted the "reverse payment settlements" terminology in *Actavis*, and for ease of reference, I will do the same throughout this Article.

3. *Actavis*, 133 S. Ct. at 2230–31, 2237–38.

from other services for which it might represent payment, and the lack of any other convincing justification."[4]

In rejecting the scope of the patent test, the Court noted 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."[5] Yet even as it acknowledged the relevance of patent law, the Court asserted that a "large" payment by the innovator to the generic company could signify a weak patent.[6] This dicta seems to reflect some lack of appreciation for the Hatch-Waxman statutory framework and the litigation and settlement dynamics it has spawned. Similarly, the Court discussed only in cursory fashion, and ultimately deferred to the district courts, the question of the role that patent validity should play in determining the reasonableness of the settlement.[7] That question likely will remain a controversial point in an ongoing debate concerning the legitimacy of reverse payment settlements, and how it is resolved will shape the impact that *Actavis* ultimately will have on innovation within and beyond the pharmaceutical industry.

I. THE COURT'S DECISION CLARIFIES THE LEGAL STANDARD APPLICABLE TO REVERSE PAYMENT SETTLEMENTS AND SHOULD PROVIDE FLEXIBILITY FOR COMPANIES AND COURTS

First and foremost, *Actavis* brings clarity to the antitrust treatment of Hatch-Waxman settlements involving consideration flowing from innovator companies to generic competitors.[8] Prior to the Court's decision, several circuit courts of appeal had split on the issue of the appropriate lens through which to evaluate these agreements.[9]

Three courts of appeals—the Eleventh Circuit,[10] the Second Circuit,[11] and the Federal Circuit[12]—had adopted a

4. *Id.* at 2237.
5. *Id.* at 2231.
6. *Id.* at 2236.
7. *Id.* at 2236–37.
8. *Id.* at 2231, 2237–38.
9. *Id.* at 2230.
10. *See* FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012), *rev'd sub nom.* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013).

"scope of the patent" approach in the context of antitrust challenges to reverse payment settlements. Under the scope of the patent analysis, a settlement that fell within the exclusionary potential of the patent would essentially be immune from antitrust attack unless the patent was obtained by fraud or the underlying litigation was a sham.[13] This approach focused on the need to give full effect to the exclusionary power of a presumptively valid patent. It also placed a high value on resolving disputes through settlement versus protracted litigation.[14]

In contrast, the Third Circuit had held that settlements containing a transfer of value from the innovator company to the generic were presumptively illegal and that courts reviewing such agreements should proceed under a "quick look" approach.[15] The "quick look" approach effectively mimics a statutory presumption of illegality. It rests on the premise that, barring convincing evidence from defendants of the procompetitive effects of the settlement agreement, all so-called reverse payment settlements should be found to violate the antitrust law.[16]

In *Actavis,* the Court rejected both the scope of the patent and the "quick look" approaches and opted instead for the more conventional rule of reason analysis.[17] The rule of reason, the Court explained, strikes the proper balance between the goals of the patent system and those of the antitrust laws.[18] Under the rule of reason approach, courts weigh a multitude of factors including "likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations

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11. *See In re* Tamoxifen Citrate Antitrust Litg., 466 F.3d 187, 212–13 (2d Cir. 2006).

12. *See In re* Ciprofloxacin Hydrochloride Antitrust Litg., 544 F.3d 1323, 1336 (Fed. Cir. 2008).

13. *See Actavis*, 133 S. Ct. at 2230 (citing *Watson*, 677 F.3d at 1312 and describing the Second Circuit and Federal Circuit approaches as "similar").

14. *See, e.g.*, Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1075 (11th Cir. 2005) ("There is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation.").

15. *See In re* K-Dur Antitrust Litig., 686 F.3d 197, 214–18 (3d Cir. 2012).

16. *See Actavis*, 133 S. Ct. at 2237.

17. *Id.* at 2230–31, 2237–38.

18. *Id.* at 2231 (citing United States v. Line Material Co., 333 U.S. 287, 308 (1948)).

present in the circumstances,"[19] as well as specific industry context.[20]

Significantly, the Court unanimously rejected the presumption of illegality standard proposed by the FTC.[21] Writing for the majority, Justice Breyer concluded that so-called reverse payment patent settlements are too complex to meet the criterion for applying a presumptive rule.[22] Thus, the Court held that a presumption of illegality is not appropriate and the FTC must prove its case as in traditional rule of reason cases.[23] The dissenting Justices would have adopted the scope of the patent approach but joined the majority in inexorably, if implicitly, rejecting the FTC's proposed presumption of illegality standard.[24]

In its preference for traditional rule of reason analysis, *Actavis* is consistent with the Court's precedent that conduct may be condemned using a "quick look" presumption of illegality only when "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets."[25] In *California Dental*, the Court held that "quick look" treatment was inappropriate because the challenged restrictions "might plausibly be thought to have a net procompetitive effect, or possibly no effect at all on competition."[26]

Likewise, there is no basis to believe that settlements that include consideration flowing from the innovator to the generic company inevitably have an anticompetitive effect. The Court recognized this explicitly, noting that "offsetting or redeeming virtues are sometimes present" in reverse payment settlements; for example, the payment may reflect avoided litigation costs or "compensation for other services that the

19. *Id.* at 2231.
20. *Id.* at 2237.
21. *Id.*
22. *Id.*
23. *Id.*
24. *Id.* at 2243 (Roberts, C.J., dissenting) ("Our cases establish that antitrust law has no business prying into a patent settlement so long as that settlement confers to the patent holder no monopoly power beyond what the patent conferred—unless, of course, the patent was invalid, but that . . . is a question of patent law, not antitrust law.").
25. Cal. Dental Ass'n v. FTC, 526 U.S. 756, 770 (1999).
26. *Id.* at 771.

generic has promised to perform—such as distributing the patented item or helping to develop a market for that item."[27] Ultimately, by refusing to draw any bright lines in favor of or against these types of settlements, the Court determined that, as with most antitrust cases, lower courts should have the flexibility to review the details and likely consequences of the agreements on a case by case basis.[28] The rule of reason analysis allows trial courts to "structure 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 . . . ."[29]

II. THE COURT'S PERCEPTION THAT THE SIZE OF THE REVERSE PAYMENT MAY SERVE AS A PROXY FOR THE STRENGTH OF THE PATENT FAILS TO ACCOUNT FOR THE DYNAMICS OF HATCH-WAXMAN LITIGATION

In defending the administrability of a rule of reason standard in the context of reverse payment settlements, the Court stated that "the size of the unexplained reverse payment can provide 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."[30] In reaching this conclusion, the Court did not appear to take into account either the unique structure and incentives associated with the Drug Price Competition and Patent Term Restoration Act of 1984 (better known as "the Hatch-Waxman Act")[31] or the way that those elements drive Hatch-Waxman litigation.

The Hatch-Waxman Act granted certain intellectual property protections to innovators to preserve incentives for innovation, and at the same time, created a pathway for and incentives to bring generic drugs to market.[32] The Act allows

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27. *Actavis*, 133 S. Ct. at 2236.

28. *Id.*

29. *Id.* at 2238.

30. *Id.* at 2236–37.

31. Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.).

32. *See, e.g.*, Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 669–71 (1990) (explaining that the Hatch-Waxman Act had dual goals of restoring to innovators the patent protection lost during the regulatory approval process and allowing competing generic companies to conduct, during the patent term,

generic drug makers to obtain regulatory approval to market generic drugs using a radically less expensive and faster process than that required of innovator drug companies, wherein the Abbreviated New Drug Application (ANDA) essentially piggy-backs on the innovator's new drug application (NDA).[33] In contrast to the huge sums spent on bringing an innovator drug to market, the cost of preparing and filing an ANDA is about $1 million.[34] Firms pursuing this approach must show only that their generic product has the same active ingredients and is bioequivalent to a reference drug that previously has been approved.[35] Further, a company can seek approval from the FDA to market the generic drug *before* the expiration of a patent relating to the innovator drug by certifying that the patent in question is invalid or not infringed by the generic product (a "Paragraph IV certification").[36] The Hatch-Waxman Act also grants 180 days of marketing exclusivity to the first generic company (or companies) to challenge an innovator's patents and gain FDA approval for its product.[37]

From the standpoint of the generic company, one of the most attractive features of the Hatch-Waxman Act is the ability to initiate a challenge to the patent without incurring any liability in doing so. The Act includes a provision that allows companies to develop information to submit to the FDA without these activities constituting patent infringement.[38] Filing a Paragraph IV certification, in and of itself, constitutes an act of patent infringement that enables the innovator to bring a patent infringement suit.[39] The generic challenger is not required to bring products to market as a prerequisite to the challenge, and therefore, the patent holder does not sustain

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otherwise infringing activity necessary to gain regulatory approval); Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 245, 260–64 (2012).

33. *See, e.g.*,Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1296–98 (11th Cir. 2003) (summarizing Hatch-Waxman Act provisions).

34. Morris, *supra* note 32, at 262.

35. *See, e.g.*, Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1059 n.2 (11th Cir. 2005) (citing 21 U.S.C. § 355(j)(5)(B)(iii)).

36. 21 U.S.C. § 355(j)(2)(A)(vii) (2012).

37. *Id.* § 355(j)(5)(B)(iv).

38. 35 U.S.C. § 271(e)(1) (2006 & Supp. V 2011).

39. *Id.* § 271(e)(2)(A).

any damages.[40] Thus, the generic drug company's chief risks in challenging a patent typically are confined to the legal fees and FDA filing expenses that it may not recover (or may recover only after patent expiration) if it loses the litigation.

Ultimately, this combination of factors in the Hatch-Waxman Act creates significant incentives for generic drug companies to challenge patents even where the patent holder is highly likely to prevail in court. The result of these skewed incentives under the Hatch-Waxman framework is striking. In its study of authorized generic drugs, the Federal Trade Commission stated that "for a drug with [annual] brand sales of $130 million, a generic that does not anticipate [authorized generic] competition will expect a patent challenge to be profitable if it has at least a 4 percent chance of winning . . . ."[41] But even this statistic vastly understates the magnitude of generic drug companies' skewed incentives. Most innovator drugs have annual sales well over $130 million. According to one analysis, for almost 90% of innovator drug sales (measured in dollars), a first-filing generic challenger balancing upside gain under Hatch-Waxman against downside risk limited to litigation costs can justify filing a Paragraph IV certification if it believes it has a *3% chance of success* in a patent case.[42]

When a drug with significant sales is involved, it is economically rational for a generic company to challenge the patent even if there is virtually no reason to think that the patent is infirm.[43] Statistics regarding the number of

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40. *See* Gerald Sobel, *Consideration of Patent Validity in Antitrust Cases Challenging Hatch-Waxman Act Settlements*, 20 FED. CIR. B.J. 47, 51 (2010) ("Unlike the usual patent case, there are ordinarily no damages claims against the generic because Hatch-Waxman forces the litigation to occur in the period prior to marketing by the generic. As a result, no sales or profits are lost by the patentee to the generic. While patent infringement suits are often settled by compromise of a damages claim, that vehicle is typically not available in Hatch-Waxman cases." (footnotes omitted)).

41. FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT, at iii n.7 (2011), *available at* http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf.

42. Kelly Smith & Jonathan Gleklen, *Generic Drugmakers Will Challenge Patents Even When They Have a 97% Chance of Losing: The FTC Report that K-Dur Ignored*, CPI ANTITRUST CHRON., Sept. 2012, at 2.

43. *See* Morris, *supra* note 32, at 269 ("In effect, the Hatch-Waxman Act actually makes pharmaceutical patents weaker than any other type of patent by making challenges to pharmaceutical patents easier and more attractive than for any other type of patent.").

Paragraph IV certifications prove this point. According to research by Duke University economist Henry Grabowski and colleagues, 64% of innovative medicines faced a Paragraph IV patent challenge in 2008, up from just 9% in 1995.[44] Moreover, given the incentives to challenge patents, it is not unusual for drugs to attract multiple generic challengers.[45] While one could argue that the proliferation of patent challenges is nothing more than an intended consequence of the Hatch-Waxman Act, there is evidence that these challenges also have produced unintended negative impacts on innovation and the value of patents.[46]

Needless to say, the Hatch-Waxman litigation dynamics, which the Court in *Actavis* did not address, create significant challenges for innovator companies. Companies with extensive product portfolios must somehow manage the risks inherent in multiple challenges, many of which subject their most successful patents to the vagaries of litigation. The threats may be even greater for smaller pharmaceutical companies, "whose entire market value rests on protecting the patent rights that support a handful of products."[47] For these companies, "the uncertainty of litigation can be untenable—even when the company has no doubt about the validity, scope, and term of its patents."[48] Under these circumstances, it should not be surprising—nor should it be seen as an admission of weak

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44. Henry G. Grabowski et al., *Evolving Brand-Name and Generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act*, 30 HEALTH AFF. 2157, 2161 (2011).

45. *See* Bret Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 367, 377 (2010); Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 520–21 (2007) ("Highly profitable drugs with tremendous therapeutic utility should and do generally attract multiple generic challengers."); *see also* Smith & Gleklen, *supra* note 42 (showing FTC data on incentives for generic firms that do not enjoy the benefit of 180-day exclusivity).

46. At least one study suggests that Paragraph IV challenges by generic manufacturers have shortened effective patent lives by at least 1.5 years, and that this held true *regardless* of whether the challenges were successful. Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 MANAGERIAL & DECISION ECON. 491, 501 (2007).

47. CHARLES-ANDRÉ BROUWERS ET AL., BOS. CONSULTING GRP., EMERGING BIOPHARMACEUTICAL COMPANIES: ENSURING A FAVORABLE ENVIRONMENT FOR CONTINUED INNOVATION 12 (2011).

48. *Id.*

patents—that many pharmaceutical innovators quite reasonably choose to settle some Hatch-Waxman challenges, even on terms that include providing considerable value to a generic competitor.[49]

The complex nature of reverse payment settlements themselves further calls into question whether the size of the payment could fairly be used as a proxy for patent strength. The Court in *Actavis* posits a scenario where an innovator earns $50 million profits per year for its product, with ten more years remaining on the patent.[50] The Court points out that a verdict that the patent is invalid or not infringed would cost the patentee $500 million.[51] The Court then contemplates a settlement that includes an unspecified payment to the generic and an unspecified generic entry date that ultimately "keeps prices at patentee-set levels, potentially producing the full patent-related $500 million monopoly return while dividing that return between the challenged patentee and the patent challenger."[52] But this hypothetical only makes sense if the settlement provides that the generic enters the market at a date that is very close to patent expiration; that is the only way that the innovator could realize the full $500 million in profits. In reality, settlements often permit generic entry substantially before patent expiration.[53] Further, the so-called reverse

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49. Both within and outside of the Hatch-Waxman context, settlement is by far the most common method of resolving a patent dispute. *See* Marc G. Schildkraut, *Patent-Splitting Settlements & the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1048 (2004) (finding that across all patent cases, 95% are resolved by settlement).

50. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2234 (2013).

51. *Id.*

52. *Id.* at 2234–35.

53. *See, e.g.*, *id.* at 2229 (describing Solvay's settlement with generic companies Actavis, Par, and Paddock, where generics obtained licenses to market their products beginning August 31, 2015, sixty-five months before Solvay's patent expired); Brief for the Generic Pharmaceutical Association as Amicus Curiae Supporting Respondents at 12, FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 769341 (describing the settlement that provided for entry of generic Lipitor five years before patent expiration, at projected consumer savings of billions of dollars per year); Brief of Generic Manufacturers Upsher-Smith Laboratories et al., as Amicus Curiae in Support of Respondents at 23–24, FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 769339 (describing a settlement wherein one generic version of tamoxifen came to market nine years before patent expiration, while three generic companies subsequently litigated and lost patent challenges on the same drug).

payments incorporated into settlements often relate to ancillary agreements for products or services to be provided by the generic, in contrast to the Court's hypothetical naked payment for staying off the market.[54] As the Court later acknowledged, district courts must view any "payment" from the innovator to the generic in context, taking into account all elements of the settlement in order to assess the reasonableness of the agreement.[55]

III. QUESTIONS RELATING TO THE PATENT'S STRENGTH ARE LIKELY TO BE CRITICAL TO EVALUATING THE REASONABLENESS OF A REVERSE PAYMENT SETTLEMENT

The Court's statements about the size of the reverse payment and its relationship to patent strength may be read as an indication that the FTC could prove its prima facie case—at least in certain circumstances—without submitting evidence regarding the validity of the patent. However, the Court also noted that when evaluating the reasonableness of a settlement, "'the quality of proof required should vary with the circumstances.'"[56] There is nothing in the Court's opinion that prohibits an antitrust defendant from arguing that a reverse payment did not harm competition because it secured a settlement that included early entry for the generic, in contrast to the likely alternative outcome where the innovator would have won the underlying patent litigation and prevented generic entry until patent expiration.

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54. *See, e.g.*, *Actavis*, 133 S. Ct. at 2229 (noting that companies' settlement agreements described payments "as compensation for other services the generics promised to perform . . . ."); Holman, *supra* note 45, at 498 ("In many cases the 'payment' comes in the form of a side deal, i.e., an agreement ancillary to the patent settlement.").

55. *Actavis*, 133 S. Ct. at 2237 (noting that complexities inherent in reverse payment settlements support the conclusion that "the FTC must prove its case as in other rule-of-reason cases").

56. *Id.* at 2237–38 (quoting Cal. Dental Ass'n. v. FTC, 526 U.S. 756, 780 (1999)); *see also* Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 877, 885 (2007) (under the rule of reason, "the factfinder weighs all of the circumstances of a case" including "specific information about the relevant business and the restraint's history, nature, and effect" (internal quotation marks and citations omitted)).

This is not a far-fetched or hypothetical argument of the sort that would shed only "minimal light"[57] on the competitive nature of a reverse payment settlement. Patent holders often prevail in Hatch-Waxman litigation that proceeds to final judgment. Statistics show that for the 171 Paragraph IV cases litigated to court decisions between 2000 and 2009, innovator companies prevailed in 52% of them.[58] More recent data on cases decided between 2009 and 2012 support these findings,[59] and in 2012 alone, innovator companies won 72% of Hatch-Waxman cases.[60] Even the outdated and skewed figures provided in the FTC's 2002 report relied upon by reverse payment critics pegged the innovator's rate of success at a non-trivial 27.5%.[61]

Beyond these aggregate numbers, cases reveal concrete examples of pharmaceutical patent owners that settled with some generics with arrangements that have been characterized as reverse payments and early entry and subsequently litigated with other generics and prevailed, keeping these later infringers off the market. For example, after the settlement at issue in the Eastern District of New York's *In re Ciprofloxacin Hydrochloride Antitrust Litigation* case, the patent was repeatedly upheld as valid in other Hatch-Waxman litigation, meaning that absent the settlement, there likely would have

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57. *Actavis*, 133 S. Ct. at 2238 (stating that courts applying rule of reason may avoid "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").

58. *See* RBC CAPITAL MKTS. CORP., PHARMACEUTICALS: ANALYZING LITIGATION SUCCESS RATES 4 (2010).

59. Gregory Glass, *Legal Defenses and Outcomes in Paragraph IV Litigation*, 10 J. GENERIC MEDS. 4 (2013) (finding that innovator companies won 54% of Paragraph IV cases litigated to court decisions between 2009 and 2012).

60. PWC, 2013 PATENT LITIGATION STUDY: BIG CASES MAKE HEADLINES WHILE PATENT CASES PROLIFERATE 28 (2013), *available at* http://www.pwc.com/en_US/us/forensic-services/publications/assets/2013-patent-litigation-study.pdf.

61. FTC, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 19–20 (2002) (finding that, of court decisions in litigation involving forty drug products from 1992–2000, the innovator prevailed against the generic company in litigation involving eleven drug products). See Brief of Antitrust Economists as Amici Curiae in Support of Respondents at 26–27, FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 836946, for a discussion of the flaws in predicting modern litigation outcomes based on the FTC's 2002 report.

been no early entry by any generic at all.[62] The same outcome occurred after the settlements at issue in *In re Tamoxifen Citrate Antitrust Litigation*[63] were reached, and the patent was repeatedly upheld as valid.[64] Similarly, after state attorneys general blocked a so-called "reverse payment" settlement between Bristol-Myers Squibb (BMS) and Apotex involving the drug Plavix, BMS won its patent case at trial.[65]

These examples demonstrate that settlements with consideration flowing from an innovator company to a generic firm may have procompetitive effects by permitting early generic entry that would not have otherwise occurred. This is not to say that all reverse payment patent settlements should survive antitrust scrutiny, nor that the Court necessarily erred in adopting a rule of reason approach over the more deferential scope of the patent test. Nevertheless, any approach that lower courts develop in evaluating reverse payment settlements under the rule of reason should be sufficiently expansive to allow defendants to prove that, in the absence of the payment, the innovator would have prevailed (after years of costly, burdensome patent litigation), and generic entry would have been delayed until patent expiration. In other words, courts should recognize that evaluating evidence pertaining to the strength of the underlying patent may be the only means of ensuring that consumers continue to reap the benefits of these procompetitive reverse payment agreements.

As the Court acknowledged in *Actavis*, albeit in passing, there remains "a general legal policy favoring the settlement of disputes."[66] The Court downplayed the likely impact of its ruling on this policy, stating without support that "the fact that

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62. *See In re* Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 519–20 (E.D.N.Y. 2005) (summarizing results of litigation where Bayer defeated two generic companies' validity challenges on summary judgment and overcame another generic's validity challenge after a nine-day bench trial).

63. 466 F.3d 187 (2d Cir. 2006).

64. *See* Zeneca Ltd. v. Novopharm Ltd., No. 96-1364, 1997 WL 168318 (Fed. Cir. Apr. 10, 1997); Zeneca Ltd. v. Pharmachemie B.V., No. CIV.A.96-12413-RCL, 2000 WL 34335805 (D. Mass. Sept. 11, 2000).

65. Sanofi-Synthelabo v. Apotex, Inc., 492 F. Supp. 2d 353, 397 (S.D.N.Y. 2007); *see also* Sanofi-Synthelabo v. Apotex, Inc., 488 F. Supp. 2d 317, 323–34 (S.D.N.Y. 2006) (describing the parties' proposed patent settlements and the government's responses to same).

66. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2234 (2013).

a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit. They may, as in other industries, settle in other ways . . . ."[67] The FTC has likewise argued that an alternative settlement may be reached in lieu of reverse payment agreements.[68] But experts familiar with economics and the dynamics of Hatch-Waxman litigation argue that, in at least some cases, the parties may be unlikely to reach a settlement in the absence of some consideration flowing from the innovator to the generic,[69] and neither the Court nor the FTC have rebutted these statements. In fact, the FTC admits—and seems pleased by the prospect—that some cases that may have settled with reverse payments would proceed to litigation if reverse payments are not readily available.[70] But neither the Court nor the FTC have explained why the law should favor an alternative resolution, be it another settlement or patent litigation, over a procompetitive reverse payment agreement.[71] Moreover, arguments that the parties could have reached an alternative settlement and arguments that the parties would instead have pursued Hatch-Waxman litigation to a likely innovator victory are essentially different sides of the same coin—if the former is relevant to the competitive effects analysis, it is hard to fathom how the latter is not equally relevant.

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67. *Id*. at 2237.

68. Brief for the Petitioner at 39–40, FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 267027 [hereinafter Brief for the Petitioner].

69. Dickey et al., *supra* note 45, at 391–97; Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 FED. CIR. B.J. 617, 618–19, 628–31 (2005); *see also* Brief of Mediation and Negotiation Professionals as Amici Curiae in Support of Respondents at 11, FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 838156 ("Modern negotiating theory and practice confirm that single variable negotiation [e.g., limiting parties' discussion to the issue of the appropriate generic entry date] will be *less* likely to produce settlement, and less likely to produce maximum settlement value, than if the parties are allowed to trade multiple variables to advance their differently valued interests.").

70. Brief for the Petitioner, *supra* note 68, at 40 ("But in the aggregate, those judgments on the merits will reflect results more in keeping with the policies of the antitrust laws, the Patent Act, and the Hatch-Waxman Amendments than if all the cases had been settled with reverse payments.").

71. As the Supreme Court noted in another context, courts are "ill-suited to act as central planners, identifying the proper price, quantity, and other terms of dealing." Pac. Bell Tel. Co. v. LinkLine Commc'ns, 555 U.S. 438, 452 (2009) (internal quotation marks omitted).

In conclusion, the rule of reason approach contemplated in *Actavis* can work to identify anticompetitive settlements without condemning procompetitive agreements. But this balance will be achieved only if courts resist the temptation to focus on shortcuts such as the size of the reverse payment or on the potential availability of alternative settlements, while discounting evidence pertaining to the innovator's patent and the settlement as a whole that more accurately reflects the competitive effects of the agreements. Indeed, such a constrained application of the rule of reason would be little better than the "presumption of illegality" the Court explicitly rejected, insofar as it inevitably would penalize lawful patent enforcement strategies and chill pro-consumer settlements. Both the structure of the Hatch-Waxman Act and fundamental principles of patent and antitrust law dictate an approach that recognizes that any agreement that allows, in the totality of the circumstances, early entry by an infringer that would otherwise be off the market for the life of the patent has a net *procompetitive* effect, regardless of the presence—or size—of a transfer of value from the patent holder to the infringer.