Abstract

The Supreme Court's decision in *Federal Trade Commission v. Actavis, Inc*. is a challenge to conventional antitrust analysis. Conventional civil antitrust cases are decided by a preponderance of the evidence. This means that conduct challenged under the rule of reason is only condemned if the conduct resulted in more competitive harm in the actual world than a world without the alleged violation. Under conventional analysis the intent of the parties also plays only a supporting role in determining whether the conduct was anticompetitive. A holder of a valid patent has a right to exclude others practicing the patented technology. And, the patent holder is not assumed to have market power because it expended resources in maintaining exclusionary rights. *Actavis* creates doubts about these propositions in circumstances beyond the "reverse" payment settlement of a patent suit that may have delayed an alleged infringer market entry. This article explores whether applying *Actavis* logic to antitrust litigation can result in condemnation of practices where there is little chance of an anticompetitive effect, where the patent holder likely has a valid and infringed patent, where there is little reason to believe that the patent holder has market power, and where only one party, or no parties, to an agreement have an anticompetitive intent. This article also investigates whether *Actavis* creates new problems with standing analysis, damages calculations and balancing efficiencies against anticompetitive effects. Nevertheless, the lower courts have begun to extend the logic of *Actavis.* This is apparent in the condemnation of no-authorized-generic settlements.

Key Words

Actavis
Antitrust
Settlement
Patent
Generic
Sherman

Actavis, Authorized Generics, and the Future of Antitrust Law

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Introduction

The Supreme Court's *Federal Trade Commission v. Actavis, Inc.*[1] decision calls many of the basic methodologies of antitrust law into question. At its most basic, the Court condemned a cash payment from a patent holder to a potential alleged infringer that settled a patent litigation where the patent holder may have done better in the settlement and consumers may have done worse in

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[1] 133 S. Ct. at 2223 (2013).

the settlement than continued litigation of the patent claim. The lower courts have begun extending the economic logic of *Actavis* in cases concerning authorize generics, known as "no-AG" cases. In these cases, the patent holder promised to limit one form of competition with the potential alleged infringer in order to settle the patent dispute. The no-AG appellate courts could find no reasonable limitation on *Actavis* methodology that would not lead to the condemnation of the settlement. But extrapolating the economic reasoning of *Actavis* to other contexts could radically alter antitrust analysis. Among other things, *Actavis* abandons the preponderance of the evidence standard applied in civil ligation, including antitrust litigation. Now, a chance that an agreement is anticompetitive, rather than the likelihood that it is anticompetitive, can result in the condemnation of the agreement. It also relies on intent evidence of a single party rather than effects evidence to establish the violation. For some, the extrapolations of *Actavis* discussed in this article will be troubling and cast some doubt on attempts to apply *Actavis* logic outside of the narrow context addressed in the decision itself. Others might see *Actavis* as opening new avenues to challenge conduct that could not otherwise be reached.

Before *Actavis*, the following simplified description of the methodologies used under Section 1 of the Sherman Act would not have been particularly controversial. There are two categories of analysis, per se and rule of reason.[2] Rule of reason analysis can sometimes be truncated when the harm to competition appears to be fairly obvious and the efficiency rationale for the conduct appears to be fairly obscure.[3] Under the full blown rule of reason analysis, the plaintiff could satisfy its prima facie burden in one of two ways. It could show an actual anticompetitive effect that flows from an agreement.[4] Or the plaintiff could show that the defendant had market power, usually through a structural analysis.[5] The mere possession of a patent did not establish the defendant's market power.[6] As is typical of civil litigation, plaintiffs had to establish the likely adverse effects of the challenged practice through a preponderance of the evidence.[7] While intent evidence could play a supporting role in the effects analysis, it could not stand alone.[8]

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[2] The prevailing mode of analysis is the rule of reason. *See Texaco Inc. v. Dagher,* 547 U.S. 1, 5 (2006). Under the per se rule, certain conduct is presumed to be anticompetitive but even under those circumstances, some inquiry may be necessary. *See NCAA v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 104 n.26 (1984) ("Per se rules may require considerable inquiry into market conditions before the evidence justifies a presumption of anticompetitive conduct.")

[3] *FTC v. Ind. Fed'n of Dentists,* 476 U.S. 447, 458-61 (1986) [hereinafter *IFD*] (certain conduct not within any per se category condemned without proof of market definition or market power).

[4] *IFD*, 476 U.S. at 460-61.

[5] *NCAA*, 468 U.S. at 109 n.38.

[6] *Ill. Tool Works Inc. v. Independent Ink, Inc.*, 547 U.S. 28, 45-46 (2006). *See also* U.S. DOJ & FTC, Antitrust Guidelines For The Licensing Of Intellectual Property 4 (2017), [hereinafter *Revised IP Guidelines*] *available at* https://www.ftc.gov/system/files/documents/public_statements/1049793/ip_guidelines_2017.pdf.

[7] E.g., *Concord Boat Corp. v. Brunswick Corp*., 207 F.3d 1039, 1058 (8th Cir. 2000) ("Antitrust plaintiffs must prove an antitrust violation by a preponderance of the evidence") (citing *Herman & MacLean v. Huddleston*, 459 U.S. 375, 390 (1983)).

[8] *Bd. of Trade of Chi. v. United States*, 246 U.S. 231, 238 (1918) (intent evidence may help to "interpret facts and to predict consequences"); *United States v. Microsoft Corp*., 253 F.3d 34, 59 (D.C. Cir. 2001) (knowledge of intent behind challenged conduct "is relevant only to the extent it helps us understand the likely effect of the monopolist's

A Section 1 claim involving a patent also required courts to determine whether the supposed adverse effect flowed solely from the patent holder's right to exclude competitors. If it did, that ended the antitrust case.[9] One approach to resolving this issue, which this article calls "merits analysis," seeks to determine whether it was more likely than not that the patent was valid and infringed.

Another approach is known as the "scope of the patent" test. This article will refer to the test as the "*potential* scope of the patent" test in order to distinguish it from merits analysis.[10] Under this test, if the exclusion was within the description of the patent, that would end the antitrust controversy. It would not matter whether a merits analysis might determine that the patent was invalid or not infringed.

But what if adverse effect did not have to be established by a preponderance of the evidence? What if, instead, any possibility of an anticompetitive effect was sufficient to establish adverse effects? What if intent played a dispositive role in establishing effects, rather than a supporting role? What if any substantial effort by a patent holder to protect its patent established the market power of the patent? What if the exclusionary power of the patent was governed by the subjective opinion of the patent holder rather than the merits of the patent?

Actavis raises all of these "what ifs." This article explores these questions, examining the peculiarities in *Actavis* reasoning as well as its possible new applications.

Actavis analysis has several characteristics that some might perceive as flaws or inconsistencies. This may slow its extension into other antitrust contexts. *Actavis* abandons the preponderance of the evidence standard for judging whether certain agreements result in an anticompetitive effect. *Actavis* may not permit courts to account for risk profiles and this might harm consumers. Under *Actavis*, intent evidence can lead to the dispositive conclusion that conduct is anticompetitive despite a long antitrust history under which intent has only played a supporting role. It is not even the intent of all parties to the alleged anticompetitive agreement that matters. It is only the intent of a single party that is conclusive. If that party's expectations about litigation outcomes are not correct, the *Actavis* solution could make consumers worse off.

The *Actavis* Court also gave its stamp of approval to settlements that might be anticompetitive. This is particularly problematic where the settlement involves a compromise of damages rather than other forms of consideration. The *Actavis* decision eschews many other elements of conventional antitrust analysis, including the traditional means of demonstrating market power.

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conduct"); *McWane, Inc. v. FTC*, 783 F.3d 814, 840 (11th Cir. 2015) ("Anticompetitive intent alone, no matter how virulent, is insufficient to give rise to an antitrust violation.").

[9] The right to exclude others is "the essence" of the patent grant, *Dawson Chem. Co. v. Rohm & Haas Co*., 448 U.S. 176, 215 (1980), and gives a patent owner a legal "right to refuse to sell . . . [its] patented products," *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 457 (1940). *See also United States v. Gen. Elec. Co*., 272 U.S. 476, 485 (1926) ("It is only when . . . [the patent holder] steps out of the scope of his patent rights" that he comes within the operation of the Sherman Act); *Simpson v. Union Oil Co*., 377 U.S. 13, 24 (1964) (similar).

[10] This also seems in keeping with the Court's terminology in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2227 (2013): the "'exclusionary potential of the patent'" (quoting *FTC v. Watson Pharms., Inc*., 677 F.3d 1298, 1312 (11th 2012)).

The *Actavis* methodology offers no easy means of balancing efficiencies against anticompetitive effects. The methodology also falls short when applied to the measurement of damages.

On the other hand, without a strong rule, most settlements of patent disputes would be anticompetitive. *Actavis* provides a simple approach to protecting consumers in some cases. It also can address certain potential adverse effects that would go untouched by other methodologies. *Actavis*, where it works, offers an efficient means of evaluating certain settlements. As a result of these positive attributes, *Actavis* could upend conventional analysis, not only in antitrust cases involving the interface between antitrust and intellectual property, but in antitrust law generally. First, *Actavis* could spell the end of patent merits analysis. Second, it could weaken the use of the preponderance of the evidence standard in civil litigation. Even a relatively small possibility that the patent holder did not have the right to exclude might justify antitrust intervention. Third, *Actavis* raises the possibility that the plaintiff need not establish the anticompetitive effect directly or through a structural analysis. Intent evidence, in the form of a payment from the patent holder to the challenger, might be sufficient to establish market power and anticompetitive effects.

Extrapolating *Actavis* to its logical conclusions would so disrupt conventional antitrust analysis that the courts may apply *Actavis* sparingly. However, the very first group of cases that addressed noncash reverse payments, no-Authorized Generic agreements ("no-AG" agreements), suggests that *Actavis* will not be read narrowly. The lower courts could not find a limiting principle in *Actavis*. To be sure there are limitations in *Actavis* but, as we will see, there are no obvious principles behind the limitations.

This article suggests that the application of *Actavis* in other contexts depends in part on whether the courts will prefer economic substance of the *Actavis* analysis over the formalities of the analysis. There is a tradition in antitrust of economic substance dictating the result regardless of the form of the analysis.[11] Some of the lower courts have latched on to this tradition even though there is another tradition that emphasizes the importance of clear rules.[12] The elevation of substance over form may have its limits, as the weaknesses in *Actavis* may seem more glaring as the courts take *Actavis*'s economic logic farther afield.

Background

Merits Analysis

The leading IP and antitrust treatise, H. Hovenkamp, M. Janis, M. Lemley, C. Leslie & M. Carrier, IP and Antitrust (3rd ed. 2016) (hereinafter Hovenkamp et al.) provides an analysis of "Resolving IP Settlement Cases Where Inquiry into Merits of IP Dispute is Required

[11] *See United States v. Sealy, Inc.*, 388 U.S. 350, 352 (1967) ("If we look at substance rather than form, there is little room for debate."); *Continental T.V., Inc. v. GTE Sylvania Inc*., 433 U.S. 36, 58-59 (1977) (focusing on "economic effect rather than . . . formalistic line drawing"); *Eastman Kodak Co. v. Image Tech. Servs*., 504 U.S. 451, 466-67 (1992) ("Legal presumptions that rest on formalistic distinctions rather than actual market realities are generally disfavored in antitrust law.").

[12] *See Pac. Bell Tel. Co. v. LinkLine Commc'ns, Inc*., 555 U.S. 438, 452 (2009) ("We have repeatedly emphasized the importance of clear rules in antitrust law.").

(Framework Step 3)."[13] Step 3 refers to a 3 step process proposed by the authors, which this article identifies as "merits analysis." In step 1, the courts can dispose of IP settlement cases where the conduct would be lawful even if the patent was invalid or not infringed.[14] In step 2, the court need not delve into the validity of the patent claim if the conduct would be illegal even if the patent were valid and infringed.[15] If Steps 1 and 2 do not dispose of the matter, we would need to go to Step 3. In Step 3 cases, "the settlement agreement would constitute lawful use of the claimed IP right if an infringement claim was valid, but not if there were no valid IP right."[16] An issue to be explored in this article is that applying *Actavis* to these cases yields different conclusions than those set forth in this merits analysis. And, indeed *Actavis* analysis yields different conclusions than conventional antitrust analysis.

The major problem with the Step 3 cases, according to Hovenkamp et al., is that under the cover of a settlement, the parties might engage in anticompetitive behavior, such as a market division. Thus, "some care must be taken to ensure (1) that the parties did have a bona fide dispute, and that the settlement is a reasonable accommodation; and (2) that the settlement is not more anticompetitive than *a likely outcome* of the litigation."[17] According to Hovenkamp et al.:

> Permitting ex post judicial queries into the validity and coverage of settled patents may sound onerous, and may sometimes be a deal breaker. But it is necessary in our "middle set" of cases to distinguish procompetitive from anticompetitive agreements. Requiring scrutiny of the *merits* of a patent case can also serve the useful purpose of encouraging the parties to execute a less restrictive settlement agreement where such an alternative is available.[18]

Hovenkamp et al. offer a cross reference to the discussion of Hatch Waxman settlements, but do not suggest in the body of the text that the standard is anything other than the "likely outcome" of patent litigation. They footnote to a test offered by Carl Shapiro, which seems to reject the likely outcome of litigation as the standard.[19] According to Shapiro, the test ought to be whether "the proposed settlement generate[s] at least as much surplus for consumers as they would have enjoyed had the settlement not been reached and the dispute instead been resolved through litigation."[20] Shapiro is formulating a test that might enhance consumer welfare more than the likely outcome of litigation. According to Hovenkamp et al., "Shapiro's test requires calculation

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[13] H. Hovenkamp, M. Janis, M. Lemley, C. Leslie & M. Carrier, IP and Antitrust § 7.03, at 7-13 (3d ed. 2016) [hereinafter *Hovenkamp et al.*].

[14] *Id*. § 7.02[A], at 7-9.

[15] *Id*. § 7.02[B], at 7-10.

[16] *Id.* § 7.03, at 7-13. Hovenkamp et al. cite to two cases that support court inquiry into the soundness of patent settlements. *Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163, 180-81 (1931); *United States v. Singer Mfg. Co*., 374 U.S. 174, 199 (1963). *Id.* § 7.03[B], at 7-21.

[17] *Hovenkamp et al.*, *supra* note **Error! Unknown switch argument.**, § 7.03, at 7-14 (emphasis added).

[18] *Id*. § 7.03[B], at 7-21 (emphasis added).

[19] *Id*. § 7.03, at7-14, n.33.

[20] Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. Econ. 393 (2003). Because Shapiro is attempting to enhance welfare more than is achievable through litigation, Shapiro's test appears to be based on expectations of the litigation outcome.

of the odds of victory…."[21] With a few caveats not relevant here, Hovenkamp et al. "agree that this is the right basic inquiry."[22] If the footnote is intended to trump the body of the text, the authors may have already departed from merits analysis. However, there are no other hints in the chapter that the proposed analysis involves anything other than determining the likely outcome of the patent litigation.

Determining the likely outcome of litigation seems to require litigating the merits of the patent within the antitrust case. Not a single Justice in *Actavis* proposed adopting this approach. Indeed, the dissent argued that no antitrust case has ever applied the merits methodology.[23] As we will see, this creates more than a dose of confusion about how to evaluate future antitrust claims that reach step 3 of the analysis.

To illustrate merits analysis, suppose it is 90 percent likely[24] (or 51 percent likely) that patents blocking competition would be upheld in litigation. Then, an agreement that continues to block competition for the life of the patent would not be more anticompetitive than the likely outcome of litigation. As we will soon see, that is not the result under *Actavis*. The likely outcome of litigation is not relevant to the *Actavis* methodology.

As an example of the merits approach, Hovenkamp et al. hypothesize that two competitors in a patent controversy divide the market to settle the dispute. The patent holder, the infringement plaintiff, gives the infringement defendant an exclusive license to practice a disputed technology east of the Mississippi, while reserving for itself the right to practice the technology west of the Mississippi. This might be an unlawful market division and a naked per se violation of the Sherman Act in the absence of a patent.[25] If the patent were valid and infringed, however, this "would be a completely legal license of a patent because the Patent Act expressly provides that the patentee may make territorially restricted licenses."[26] The question for Hovenkamp et al. is whether the settlement "was a reasonable accommodation given both the presence of IP rights

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[21] *Hovenkamp et al.*, *supra* note **Error! Unknown switch argument.**, § 7.03, at 7-14, n.33.

[22] *Id.*

[23] *Actavis*, 133 S. Ct. at 2240 (Roberts, C.J., dissenting) ("While it is conceivable to set up a legal system where you assess the validity of patents or questions of infringement by bringing an antitrust suit, neither the majority nor the Government suggests that Congress has done so."); *Id*. at 2242 ("The majority points to *no* case where a patent settlement was subject to antitrust scrutiny merely because the validity of the patent was uncertain. Not one. It is remarkable, and surely worth something, that in the 123 years since the Sherman Act was passed, we have never let antitrust law cross that Rubicon.") (emphasis in the original).

[24] It is not implausible that a generic would challenge the patent of the brand through a Paragraph IV certification even if it believes it is 90 percent probable that the brand would prevail. For a branded drug with $130 million in annual sales, the FTC estimated that generic entry in the face of a patent challenge from the brand-owner is profitable so long as the generic has at least a four percent chance of winning. The odds of winning required for generic entry to be ex-ante profitable are even lower for drugs with larger sales. Federal Trade Commission, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact, iii n.7 (2011), *available at* https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

[25] *Hovenkamp et al.*, *supra* note **Error! Unknown switch argument.**, § 7.3[A], at 7-17.

[26] *Id*.

and the scope of their claims."[27] Presumably this is answered by determining the likely outcome of litigation of the patent claim. If it is more likely than not that the patent holder would prevail in litigation, the market division is legal. To determine that, there would have to be a patent trial within the antitrust trial and the antitrust defendants (the patent holder and the alleged infringer) would prevail if the fact finder concludes by a preponderance of the evidence that the patent was valid and infringed.

Hatch Waxman Background

The Drug Price Competition Act of 1984, known as the Hatch Waxman Act attempted to facilitate entry of generic drug manufacturers while protecting branded drug manufacturers' patent rights covering their pharmaceuticals. Under the Act, when a branded drug manufacturer seeks Food and Drug Administration (FDA) approval to distribute a new drug, the manufacturer will have to go through years of testing regarding safety and effectiveness of the drug. The outcome of this testing will be reflected in a New Drug Application (NDA). The manufacture would also list in the NDA any patents that cover the new drug.[28]

A generic need not retest its proposed drug if it can show that the drug has the same active ingredient and is bioequivalent so that it can rely on the brand's safety and effectiveness studies, without compensating the brand-owner for any portion of the cost of the studies done to put the drug on the market initially.[29] The generic would seek approval by filing an Abbreviated New Drug Application (ANDA).[30] If the brand had listed patents in its NDA, the ANDA must provide one of four certifications regarding the generic's legal ability to manufacturer in light of those patents.[31] The certification pertinent here is known as the Paragraph IV certification, under which the generic claims that its drug will not infringe the brand's patent or that the brand's patent is invalid.[32] The generic must provide notice to the brand of its basis for the belief that the patent is either invalid or not infringed.[33]

After receiving notice, the brand has 45 days to file an infringement law suit.[34] In the absence of the filing of the infringement complaint, the FDA can make the ANDA approval effective immediately,[35] but if the lawsuit is timely filed, the ANDA approval can only become effective

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[27] *Id*. at 7-18.

[28] 21 U.S.C. § 355(b)(1).

[29] The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), also requires studies to have new pesticides approved and to keep existing pesticides on the market. Unlike Hatch-Waxman, FIFRA provides that new (generic) entrants pay a portion of the costs of these studies. For a recent decision concerning such data compensation arising under FIFRA. *See Drexel Chem. Co. v. Albaugh, Inc.*, No. 14-6340/6363 (6th Cir. May 18, 2016), *available at* http://admin.taftlaw.com/linked_documents/0000/1679/Drexel_Chem._Co._v._Albaugh__Inc..pdf.

[30] 21 U.S.C. § 355(j)(2)(A)(iv).

[31] *Id*. § 355(j)(2)(A)(vii).

[32] *Id*. § 355(j)(2)(A)(vii)(IV).

[33] *Id*. § 355(j)(2)(B)(i-iv).

[34] *Id*. § 355(j)(5)(B)(iii).

[35] *Id*.

upon the expiration of a 30-month period (which can be adjusted by the court entertaining the patent claim).[36] If the court renders a final decision that the patent is invalid or not infringed, within the 30 month period, the ANDA approval is effective on the date of the final decision. Nothing, however, in Hatch-Waxman prevents the generic with an approved ANDA from entering "at risk" after the initial 30-month period has elapsed and some generics have done so.

The first generic to file obtains a 180-day exclusivity period where it is free from the competition of other third party generics. The period starts to run only when the first filer begins selling the generic drug.[37] This creates a possible bottleneck that enhances the litigating party's opportunity to settle the Hatch Waxman litigation through a net reverse payment from the brand to the generic in return for the generic delaying entry, thereby precluding the entry not only of the first generic filer but the entry of all later filers for some time.[38] We use the term "net reverse payment" to indicate a reverse payment that is larger than could be justified by avoided litigation costs and by anything of value that the generic provides to the brand in exchange for the settlement, e.g., a valuable cross license.

Applying Merits Analysis to Hatch Waxman

It is worth considering how the courts might apply merits analysis to a Hatch-Waxman agreement where a specific entry date is traded for a net reverse payment. Suppose the brand has ten years left on its patent and settles the litigation with the generic by giving the generic money and splitting the patent life, such that the generic may enter in six years. Under step 1, we evaluate whether the agreement would be lawful in the absence of the patent. We appear to have a market division agreement (the market being divided in terms of time). The court may not apply the per se rule because the settlement of patent litigation offers a context that is different from past market division agreements condemned per se.[39] If it is not addressed under the per se rule, the court would have to analyze whether the brand has market power.[40] Because the courts no longer presume that a patent gives the patent holder market power,[41] the analysis would likely involve defining the market, measuring market concentration and assessing entry conditions.[42] If

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[36] *Id*.

[37] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. § 355(j)(5)(B)(iv). The generic must enter in a reasonable time. *Id*. § 355(j)(5)(D)(i)(l).

[38] Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, a first filer may forfeit its exclusivity if it does not begin marketing the drug at issue within 75 days of a final, nonappealable court judgment that the first filer's product does not infringe the brand-name's patents. 21 U.S.C. §§ 355(j)(5)(D)(i)(I)(bb), (D)(ii). Alternatively, first-filer exclusivity can be forfeited if another generic manufacturer successfully challenges the brand-name patents at issue and if the first filer fails to market its generic within 75 days of a final, nonappealable judgment in that other manufacturer's suit. *Id*. This limits, but does not eliminate, the extent to which the first filer can create a competition bottleneck.

[39] *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 607-08 (1972) ("It is only after considerable experience with certain business relationships that courts classify them as per se violations of the Sherman Act.")

[40] *Copperweld Corp. v. Indep. Tube Corp*., 467 U.S. 752, 768 (1984); *NCAA*, 468 U.S. at 109 n.38.

[41] *Ill. Tool*, 547 U.S. at 45-46.

[42] *Flegel v. Christian Hosp.*, 4 F.3d 682, 689 (8th Cir. 1993). Actual effects analysis could rarely be used to assess the competitive effects of Hatch Waxman settlements because the generic remains off the market as a result of a 30-month automatic preliminary injunction. An actual effects analysis would focus on whether entry resulted in lower

the conclusion is that the agreement is per se unlawful or that market power is present, the answer to the question about whether the agreement would be lawful in the absence of a patent is "no."

Under step 2, we ask whether the agreement would be unlawful if the patent is valid and infringed. The answer is "no," because the patent would then legally block the generic's entry. Indeed, it would block entry for the entire life of the patent. If the answer to the first two questions is "no," Hovenkamp et al. would classify the settlement here as a middle case or difficult case that requires an analysis of whether "the settlement is not more anticompetitive than *a likely outcome* of the litigation."[43] This would seem to require litigating the patent case inside the antitrust case. If the fact finder determines that it is more likely than not that the brand's patent would withstand the generic's challenge, the settling parties would not be liable under the antitrust law. Indeed, by settling for the 6 year/4 year split of the patent life, the parties provided more competition than merits analysis would demand.

Pre-*Actavis* Analysis of Hatch Waxman Settlements

Prior to *Actavis*, the courts were split on the proper way to analyze Hatch Waxman settlements with net reverse payments. In a rather terse opinion, the Sixth Circuit held that such reverse payments were per se unlawful.[44] The Federal Trade Commission held that net reverse payments were presumptively unlawful.[45] The Eleventh Circuit in *Valley Drug Co. Inc. v. Geneva Pharmaceuticals, Inc*.[46] seemed to apply merits analysis, holding that the reverse payment settlement would be lawful if patent holder would have won the Hatch Waxman patent suit but unlawful if it would have lost. However, in reviewing the Federal Trade Commission's *Schering Plough* decision, the Eleventh Circuit applied the potential scope of the patent test: the reverse payment settlement would only be unlawful if the settlement exceeded "the scope of the exclusionary potential of the patent."[47] This did not appear to leave any room for merits analysis. If the patent had not been invalidated and the generic's drug was within the description of the patent, the court would presume the legality of the settlement.[48] Several other courts were as deferential as the *Schering Plough* court.[49] The Third Circuit, however, was not. Reviewing the same settlements that the FTC and the Eleventh Circuit had reviewed in *Schering Plough*, it

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prices, lower output or similar actual effects. But if the generic is still off the market, there is no difference in pricing or other competitive dimensions to demonstrate the effect. Actual effects analysis could be used in the rare situation where the litigation occurs after an at-risk entry after the preliminary injunction expired as generic entry into the market may show a fall in prices.

[43] *Hovenkamp et al.*, *supra* note **Error! Unknown switch argument.**, § 7.03, at 7-14 (emphasis added).

[44] *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

[45] *In re Schering Plough Corp*., No. 9297 (F.T.C. Dec. 18, 2003), *rev'd Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

[46] *Valley Drug Co., Inc. v. Geneva Pharms. Inc.*, 344 F.3d 1294, 1312-13 (11th Cir. 2003).

[47] *Schering-Plough*, 402 F.3d at 1066.

[48] *Id.* at 1068.

[49] *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212-13 (2d Cir. 2006); *In re Ciprofloxin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1335 (Fed. Cir. 2008).

concluded that a net reverse payment was prima facie evidence of an unreasonable restraint of trade.[50]

Federal Trade Commission v. Actavis

In *Federal Trade Commission v. Actavis, Inc*.,[51] Solvay Pharmaceuticals paid various amounts to several generics, including Actavis, to delay generic entry for several years or in some cases for the generic to drop its challenge. The Eleventh Circuit had ruled for the antitrust defendants, applying the potential scope of the patent test.[52] The Supreme Court reversed, rejecting that test, in a 5-3 decision authored by Justice Breyer. According to the Court, whether the generic's drug was within the potential scope of the patent did not mean that the patent was valid. The Court reasoned that patent validity was the point of the Hatch Waxman litigation and if the patent was found invalid in that litigation, the patent holder would have no right to exclude.[53] On the other hand, just because the brand's patent might be valid and infringed did not mean that the settling parties were out of the antitrust woods. The issue was not merely the right to exclude under the patent law because "it would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent policy, rather than by measuring them against procompetitive antitrust policies as well."[54] According to the Court, "what the holder of a valid patent could do does not by itself answer the antitrust question."[55] Thus, the right to exclude others from practicing patented technology has to "accommodate patent and antitrust policies."[56] In other words, "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly.'"[57]Whether a restraint "lies 'beyond the limits of the patent monopoly' is a *conclusion* that flows from [the antitrust] analysis."[58]

When considering antitrust policy, the Court pointed out that net reverse payment settlements had the "potential for genuine adverse effects on competition."[59] The Court was concerned that the settlement would keep prices at the monopoly level, and that the reverse payment divided these monopoly returns between the brand and the generic.[60] While the antitrust defendants would have an opportunity to justify the payment,[61] such a payment and the ensuing

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

[51] *Actavis*, 133 S. Ct. at 2223.

[52] *Watson,* 677 F.3d at 1312.

[53] *Actavis*, 133 S. Ct. at 2231.

[54] *Id.*

[55] *Id*. at 2230-31.

[56] *Id*. at 2233.

[57] *Id.* at 2231.

[58] *Id*. at 2231-32 (emphasis in the original) (quoting *Id.* at 2240 (Roberts, C.J., dissenting)).

[59] Id. at 2234 (quoting *IFD*, 476 U.S. at 460-461).

[60] *Id*. at 2234-35.

[61] *Id*. at 2236.

anticompetitive consequences would "sometimes prove unjustified."[62] The Court went on to say that where a reverse payment threatened to result in such unjustified anticompetitive effects, the patent holder likely possesses the market "power to bring that harm about in practice."[63]

The Court did observe that "a *valid* patent excludes all except its owner from the use of the protected process or product."[64] At first blush, this would suggest that the parties would need to litigate the patent merits in the antitrust case. But according to the Court, "it is normally not necessary to litigate patent validity to answer the antitrust question."[65] The Court explained, "[a]n unexplained large reverse payment itself would normally suggest that the patentee had serious doubts about the patent's survival."[66] Indeed, according to the Court, "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness."[67] The Court did not elaborate on how to use the size of the payment to judge a patent's weakness.

Because a reverse payment settlement posed the danger of anticompetitive effects, but could be potentially justified, the Court instructed the lower courts to evaluate such settlements under the rule of reason. It observed that the "likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of other convincing justification."[68] The Court observed, however, that it might not be necessary to consider "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."[69]

Understanding *Actavis*

To delve more deeply into reverse payments, payments for delay or exclusion payments, we first must define "anticompetitive." The logic of *Actavis* suggests that "anticompetitive" means a reduction in rivalry that harms consumers in a static sense by staving off a decline in average price levels due to a delay in generic entry.[70]

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[62] *Id*. at 2235-36. The justification cannot be "a desire to maintain and to share patent-generated monopoly profits." *Id.* at 2237.

[63] *Actavis*, 133 S. Ct. at 2236.

[64] *Id*. at 2231 (emphasis in the original) (quoting *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948)).

[65] *Id.* at 2236.

[66] *Id*.

[67] *Id*. at 2236-37.

[68] *Id*. at 2237.

[69] *Id*. at 2238.

[70] There may be not only a downward price effect on the first day of generic entry, but a more severe effect in the longer term. According to an FTC study, the first generic entrant, with 180-days of exclusivity, priced its version at about 15 percent lower than the brand. AUTHORIZED GENERIC DRUGS 35, *supra* note **Error! Unknown switch argument.**. As other generics entered the market, the generic prices end up about 85 percent lower than the pre-generic brand price. Federal Trade Commission, Pay-For-Delay: How Drug Companies Pay-Offs Cost Consumers

A dynamic analysis would address the extent to which settlements that reduce consumer surplus in the short run might enhance consumer surplus in the long run by encouraging investment.[71] Such dynamic considerations are beyond the scope of this article. Another issue that will not get the full consideration it deserves here is the effect of generic entry on patient compliance with the prescribed medication regimen. The brand has a substantial incentive to use its sales force to coax doctors to remind their patients to continue to take the drug as prescribed. This seems to sometimes affect compliance. Once generics enter the market, the brand's incentive to engage in such compliance activities diminish because the activity might only encourage the patient to continue to take the generic.[72] For certain pharmaceuticals, at the same time that generic entry results in reduced average prices for the pharmaceutical, the total sales of the pharmaceutical falls.[73] This might be an issue worthy of rule of reason analysis in a net reverse payment settlement case.[74]

Bribing Generics to Stay Out of the Market

Using the implicit *Actavis* definition of "anticompetitive," in the absence of any limitations on settlements and in the presence of some market power, payments from the brand to the generic might very well generate anticompetitive results. A branded company with market power would have a substantial incentive to bribe the generic to stay out of the market for the remaining life of the patent. The branded company could then continue to charge monopoly prices until the patent expires. The generic would also be incented to enter into such an agreement and share in the benefit of this monopoly pricing through the bribe it received, which as explained below can easily exceed expected profits from competing.

Billions 8 (2010), *available at* https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

[71] *See* James Langenfeld & Wenqing Li, *Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreement with Payments from Branded to Generic Drug Manufacturers*, 70 Antitrust L.J. 777, 778 (2003).

[72] For the impact of direct to consumer advertising on consumer compliance, *see* Julie M. Donohue et al., *Effects of Pharmaceutical Promotion on Adherence to the Treatment Guidelines for Depression*, 42 Med. Care 1176 (2004); John E. Calfee et al., *Direct-to-Consumer Advertising and the Demand for Cholesterol-Reducing Drugs*, 45 J.L. & Econ. 673(2002).

[73] P.J. Huckfeldt & C. R. Knittel, *Pharmaceutical Use Following Generic Entry: Paying Less and Buying Less* (Nat'l Bureau of Econ. Research, Working Paper No. 17046, 2012); D. Lakdawalla, T. Philipson, & R. Wang, *Intellectual Property and Marketing* (Nat'l Bureau of Econ. Research, Working Paper No. 12577, 2006); F. Lichtenberg & G. Duflos, *Time Release: The Effect of Patent Expiration on U.S. Drug Prices, Marketing, and Utilization by the Public*, Medical Progress Report, No. 11 (October 2009); E. Berndt, M. Kyle, & D. Ling, *The Long Shadow of Patent Expiration: Generic Entry and Rx-to-OTC Switches*, Scanner Data and Price Indexes, 2003.

[74] Other issues that might be worthy of analysis in some cases is the loss of brand discounts for low income patients and free samples. Henry Grabowski, Tracy Lewis, Rahul Guha, Zoya Ivanova, Maria Salgado, & Sally Woodhouse, in *Does Generic Entry Always Increase Consumer Welfare?*, 67 Food and Drug Law J., 373, 389 (2012) provide an example concerning oral contraceptives. The market had many providers with patented products/dose forms. Due to the underlying competition, the value of generic entry AB-rated to one of the brands was estimated to be small in terms of price—total value of $25.8 million per year. But the value of the lost free-samples was estimated to be $69.8 million.

The branded company with substantial market power emanating from a patent should be able to bribe the generic to stay out of the market because of an asymmetry affecting the brand's and the generic's future profit streams. When the generic enters, the brand loses its monopoly profits on the drug, but the generic does not gain the monopoly profits that the brand lost. Rather, both brand and generic capture more ordinary profits due to lower prices resulting from the intensified competition.[75] The brand will thus willingly offer the generic an exclusion or net reverse payment to retain most of its monopoly profits. The generic will accept the payment so long as it is more than it expects it will earn by litigating and competing. It is a win-win proposition. Or actually, it is a win-win-lose proposition; the losers being the consumers. They pay more for the branded drug than they would have paid if the generic had entered earlier. So if the primary concern is benefiting consumers in a static sense, it does seem that we need some rules to limit Hatch-Waxman settlements.

Hypotheticals[76]

Under *Actavis,* settling Hatch-Waxman litigations by splitting the patent life without a reverse payment is lawful.[77] For example, suppose there is ten more years to the life of the patent at the point of the Hatch-Waxman settlement. The litigants might settle by "splitting" the patent life pursuant to which the generic agrees to stay out of the market for the next several years and the parties agree that they will compete thereafter. A problem arises when the splits are facilitated by a net reverse payment. This split of the patent life and what motivated that split offers a good vehicle for describing the competitive properties of *Actavis* and other potential antitrust methodologies. Below we offer several hypotheticals that illustrate the point.

We simplify the analysis by ignoring net present value calculations, by assuming that the settlement occurs early in what would be a costly litigation but that the litigation occurs instantaneously if there were no settlement, and by assuming that that the manufacture and distribution of the drugs at issue are costless. We begin by assuming no risk aversion, though we will later alter that assumption.

Hypothetical 1: the litigants' expectations about litigation are correct.

Consider a brand that has ten years left on its patent and expects to earn a $1 billion per year. It believes it has a 40 percent chance of prevailing in Hatch-Waxman litigation. It believes that if the generic enters, the brand's profits would fall to $100 million per year. A 40 percent chance of attaining $1 billion per year for ten years equals $4 billion. A 60 percent chance of obtaining $100 million per year for ten years equals $600 million. The brand's expected value of litigation is thus $4.6 billion (ignoring litigation costs).

In this hypothetical, the generic's expectations regarding the litigation are aligned with the brand's expectation. And, it believes that it too will make $100 million per year if it prevails in

[75] To simplify the analysis, in various hypotheticals we assume there will not be multiple generic entrants.

[76] The hypotheticals involve more severe downward price effects than may occur on the first day of generic entry and may be more reminiscent of long term effects. *See* note 70, *supra*.

[77] *Actavis*, 133 S.Ct. at 2237.

the litigation. It believes that there is a 40 percent chance that it will lose and generate no profits. It believes there is a 60 percent chance of obtaining $100 million per year for ten years, $600 million in total. Hence, the generic's expected value of litigating to verdict is $600 million (ignoring litigation costs). With this alignment on litigation expectations, the parties ought to be able to settle the litigation by splitting the patent life in a way that satisfies their expectations. In the settlement, the patent holder will retain its monopoly for four years. It will make $4 billion in those four years. The generic will be able to enter in year five. The brand and the generic will each make $100 million in years five through ten. By splitting the patent life in this fashion, the brand realizes the expected value of the litigation, $4.6 billion, and the generic realizes its expected value of $600 million. The incentive to reach this settlement is avoiding the costs of litigation.

The *Actavis* majority would endorse this settlement.[78] But oddly, the majority also found that the evil in reverse payment settlements is that such an agreement would "prevent the risk of competition. And … that consequence constitutes the relevant anticompetitive harm."[79] However, our hypothetical suggests that a net reverse payment is not the only situation where a settlement prevents the risk of competition. Under the hypothetical, the brand avoids the 60 percent likelihood of ten years, rather than six years, of competition even though there is no net reverse-payment. In other words, it is more likely than not (if the parties' expectations are correct) that there would be ten years of competition and the settlement results in only six years. The dissent pointed out this flaw in the majority's reasoning.[80]

As for the consumers of the drug in question, they will expect to pay $5.2 billion on average for the drug over ten years whether the parties litigate (if the parties' expectations are correct) or settle. Consumers are thus doing as well *on average* as they would do if the litigation continued *assuming* that the litigants' expectations on the outcome are correct. This may explain why the *Actavis* majority does not find the settlement problematic even though consumers lose the 60 percent chance that they would pay $2 billion for the drug rather than $5.2 billion.

Given that this settlement is lawful under *Actavis* (and the *Actavis* dissent would have no problem with this outcome either), there seems to be something fundamentally wrong with the majority's concern about eliminating the risk of more competition. Despite the majority's loose language about eliminating risk, the fairly clear economic objective of *Actavis* is not to prohibit the elimination of risk but rather to eliminate adverse effects on the *average* consumer under the assumption that the litigants are prescient about the litigation outcome.

Notice, however, the tradeoff for the median consumer: assume that there are ten Hatch Waxman litigations with the same probabilities and the same payoffs. The generic would prevail in six out of the ten litigations and consumers of those six drugs would pay $2 billion for each of those drugs over the ten years. But in four of the ten litigations, consumers would pay $10 billion for each drug. So in six out of ten cases, the consumers would have been better off with litigation

[78] *Id.*

[79] *Id.* at 2236.

[80] *Id.* at 2245 (Roberts, C.J., dissenting) (any settlement "takes away some chance that the generic would have litigated until the patent was invalidated").

and in four out of ten they would have been better off with the settlement. If there were the same number of consumers using each drug, there are more losers than winners in the settlements that the *Actavis* majority would permit. Nevertheless, a risk-neutral consumer might be indifferent to the *Actavis*-inspired settlement compared to continued litigation. While the median consumer has a 60 percent chance of doing better if the parties are forced to litigate, there is a 40 percent chance that the median consumer will be paying significantly higher prices for ten years rather than six. The 40 percent chance of higher (monopoly) prices offsets the 60 percent chance of lower prices, leaving the median consumer indifferent to the outcome of litigation versus settlement.

Averages, however, may hide the impact on some consumers. There may be vulnerable consumers that cannot afford to pay the branded price and they may not be able to purchase the drug during the six years the brand retains its exclusive. These consumers may prefer continued litigation if doing without the drug for six years is out of the question *and* generic entry would make it available. The litigation gives them a 60 percent chance that they will be able to afford the drug. The settlement that *Actavis* would approve provides quite a contrast to conventional antitrust thinking that reveals a reluctance to trade off one set of consumers for another or one sector of the economy for another.[81]

If we apply the merits analysis to the settlement in this hypothetical, we first conclude there may be an antitrust problem if the patent holder has market power and does not have the right to exclude. In fact, there is a market division agreement: the litigants have divided the market in terms of time.[82] We next ask whether the settlement would be unlawful even if the patent was valid and infringed. The answer is "no;" it would not be unlawful because the settlement is no more (actually less) exclusionary than the patent itself. Thus, under merits analysis, the patent life splitting in the settlement requires litigating patent validity and infringement issues within the antitrust litigation.

If the parties' assessment of the patent litigation is correct, six out of ten juries would find that the brand does not have a valid patent or that the patent was not infringed and that finding would

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[81] *See Topco*, 405 U.S. at 610-112:

> Topco has no authority under the Sherman Act to determine the respective values of competition in various sectors of the economy. . . . If a decision is to be made to sacrifice competition in one portion of the economy for greater competition in another portion this too is a decision that must be made by Congress and not by private forces or by the courts. Private forces are too keenly aware of their own interests in making such decisions and courts are ill-equipped and ill-situated for such decision making. To analyze, interpret, and evaluate the myriad of competing interests and the endless data that would surely be brought to bear on such decisions, and to make the delicate judgment on the relative values to society of competitive areas of the economy, the judgment of the elected representatives of the people is required.

See also U.S. DOJ & FTC, Horizontal Merger Guidelines § 10, at 30, n.14 (generally refusing to trade off one set of consumers for another when evaluating efficiencies); Dale Collins, Beau Buffier, Jessica Delbaum, Address at the Bay Area Antitrust Seminar Series (October 19, 2010.

[82] *Addyston Pipe & Steel Co. v. United States*, 175 U.S. 211, 240-41 (1899) (allocation of business among competitors is "necessarily a restraint upon interstate commerce"). The *Actavis* Court cited to an earlier Supreme Court market division case. 133 S. Ct. at 2227 (citing *Palmer v. BRG of Ga.*, Inc., 498 U.S. 46 (1990) (per curiam)).

be upheld on appeal, condemning the settlement. Four out of ten juries would find the opposite, vindicating the settlement.

With a 60 percent chance that the antitrust verdict would go against them, the expected cost of a settlement that splits the patent life, even with no net reverse payment, would seem to be high. So the Hatch Waxman litigants might not settle if they expect that merits analysis would apply instead. They would continue the litigation and the litigation's outcome will dictate the level of competition that consumers enjoy.

If the party's assessment of the patent litigation's outcome were correct, the parties and the court system would find the *Actavis* solution superior to merits analysis. They prefer the patent splitting settlement because they can avoid the cost of litigation and get the expected value of litigation. Consumers appear to be indifferent on average.[83] Of course, the parties' expectations about litigation may not be correct and consumers may be better off or worse off with the patent-splitting settlement—topics for additional hypotheticals.[84]

The *Actavis* dissent has no problem with the patent splitting outcome, either. But the *Actavis* dissent would seem to permit any size payments so long as the resulting exclusion is within the potential scope of the patent. In hypothetical 1, the brand pays the generic something more than $600 million to keep the generic off the market for the entire term of the patent. The brand retains up to just below $9.4 billion in profits. Both litigating parties benefit from a reduction in litigation costs as well. Consumers, on the other hand, will pay $10 billion for the drug at issue over ten years when they would have paid only $5.2 billion under settlements that have the *Actavis* stamp of approval.

The key learnings from this hypothetical are, first, that certain outcomes that are not necessarily acceptable under the merits analysis are acceptable under *Actavis*. Second, *sometimes* the *Actavis* methodology can achieve the average outcome of merits analysis at a much lower cost (assuming the parties' prescience). Third, a brand that is unlikely to prevail in patent litigation can still settle by dividing the market. Fourth, the *Actavis* majority is not troubled by a settlement that eliminates litigation risk if there is no net reverse payment motivating the settlement. Fifth, consumers can be much worse off if the Court had adopted the potential scope of the patent test apparently endorsed by the *Actavis* dissent.

[83] Actually, the average consumer is not totally indifferent. *On average*, consumers are no better off as a result of the continued patent litigation versus the patent-splitting settlement. But consumers are also tax payers and they benefit ever so slightly by the settlement because tax payers bear the court's cost of continued litigation.

[84] The analysis that consumers are indifferent on average has not yet fully taken account of situations where there is a high probability that the brand will prevail. Under these circumstances, the generic might not seek Paragraph IV certification. It might not be worth the generic's effort if chances of prevailing are remote. This might be counterbalanced by occasions where the brand recognizes its weak chance of prevailing and acts accordingly. But loss aversion might be a powerful phenomenon keeping the brand in litigation. So it is unclear how these incentives bias the outcome for consumers.

Hypothetical 2: The parties both believe that the brand holds a "strong" patent.

"Strong" is in the eye of the beholder, but most would agree that a patent is strong if both litigating parties believe the brand is 90 percent likely to prevail, as is hypothesized here. Using the same elements as hypothetical 1, other than the parties' expectations, in a mutually beneficial settlement, the generic agrees to stay out of the market for the ten year patent term in exchange for a $100 million reverse payment. The brand is about $800 million better off (minus litigation costs) over litigation assuming the parties' expectations are correct. The generic is better off because it avoids litigation costs. The consumers are worse off because they will pay $1 billion for the drug in year ten rather than $200 million

This change in the hypothetical illustrates that the *Actavis* majority was wrong when it claimed that a reverse payment "can provide a workable surrogate for the patent's weakness…."[85] It does nothing of the sort as the brand has an incentive to pay the generic to stay out of the market even if the parties agree that the patent is very strong. In fact, *Actavis* acknowledged this in the three sentences before the quoted language, where the Court states:

> The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm.[86]

We can make sense out of this "weakness" terminology if we take the Court to mean that the patent is weak relative to the terms extracted in settlement. That is, the 90 percent patent is weak compared to the brand obtaining 100 percent of the patent life.[87] We can also make sense of the "weakness" terminology if we take the Court to mean that consumers are better off on average with litigation than with the settlement (assuming the parties' expectations regarding litigation are correct). But it is hard to reconcile these rationales with the majority's conclusion that "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival."[88]

Hypothetical 3: No alignment in expectations.

Assume that the litigants are not aligned on the probable outcome of the litigation. Both believe they have a 60 percent chance of victory. Because of our assumption that billions of dollars are at stake, the avoidance of litigation costs will not be sufficient to drive a settlement. Nor can the parties barter time on the market to reach settlement because they value time differently. For example, if the patent life were split at five years, 50-50, the generic would be able to enter in

[85] *Actavis*, 133 S. Ct. at 2236-37.

[86] *Id*. at 2236.

[87] *See* Aaron Edlin et al., *Activating Actavis*, 28 Antitrust, No. 1, 16-17 (2013); Joshua B. Fischman, *The Circular Logic of Actavis*, 66 Am. Univ. L. Rev. 91, 109 (2015).

[88] *Actavis*, 133 S. Ct. at 2236.

year six. The brand would be out the $1 billion it believes it would make in year six and the generic would be out the $100 million that it believes it would make in year five.

The brand would not offer the generic a sufficient bribe to reach a settlement that gives it a six year exclusive because it would cost the brand the $1 billion it expects to make in that year. In the absence of risk aversion, the brand will only be willing to offer the generic the cost of litigation to achieve a six year exclusive. But the generic, with an expectation of six years of competition would demand $200 million (less litigation costs) to settle for only five years of competition.

It seems like no settlement is possible, but wait: the brand could attempt to get more than its expected value of litigation. Instead of bribing the generic to get a 60/40 split, it offers the generic $600 million to get a 100/0 split. With a perceived 60 percent chance of prevailing, its expected value of litigation is $1 billion per year times six years plus $100 million per year times four years, which equals $6.4 billion (less litigation costs). The generic's expected value of litigation is six years times $100 million, which is $600 million (less litigation costs). The generic avoids the litigation costs by settling.

The *Actavis* majority would condemn the settlement that could end the litigation. The *Actavis* dissent would not find the settlement troubling. Under merits analysis, the settlement would be vindicated between 40 and 60 percent of the time (assuming one of the party's expectations is correct). But the parties might not be willing to take the risk of merits analysis. Consider the risk from the perspective of the generic, which would be jointly and severally liable if it loses the antitrust litigation.[89] The generic believes it has a 40 percent chance of losing the antitrust litigation. There are two elements to its expected value of the hypothesized settlement. The first element is 60 percent of the $600 million settlement; that is, the 60 percent expectation that the defendants would prevail and the generic gets to keep the $600 million settlement. The second element is the 40 percent chance that damages would be awarded. If damages were awarded, the damages will be calculated over the entire ten year period that the generic would have been competing with the brand, but for the settlement. In that period, consumers paid $10 billion, but would have only paid $2 billion if the parties had competed for the entire period. That is $8 billion in damages. The settlement relieved the generic of paying to litigate the patent suit but it had to pay to litigate the antitrust suit. And of course, if it lost the antitrust suit, it would have to cover plaintiff's litigation costs.[90] Then, of course, there is the trebling of damages.[91] It does not seem worthwhile for the generic to settle.[92]

The key learnings here are that, first, sometimes no settlement is possible, even with a net reverse payment, if the brand wants to settle for the expected value of Hatch-Waxman litigation.

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[89] *City of Atlanta v. Chattanooga Foundry & Pipeworks*, 127 F. 23, 26 (6th Cir. 1903), *aff'd on other grounds*, 203 U.S. 390 (1906).

[90] 15 U.S.C. § 15(a).

[91] *Id*.

[92] We must take care not to over-emphasize the incentives to avoid antitrust litigation as there seems to be no shortage of such litigation. Nevertheless, to the extent it does sway litigants' behavior, it re-enforces the notion that the Court's decision was intended to minimize litigation costs.

Second, there is a substantial chance that the settling parties would be vindicated in an antitrust lawsuit using merits analysis assuming that one of the parties' perceptions of the Hatch-Waxman litigation outcome are correct. But it may not be worth the parties' while to risk such a lawsuit. Under our definition of "anticompetitive," the settlement is anticompetitive as the settlement has a lower expected value for consumers than continued litigation.

From the *Actavis* perspective, the settlement is anticompetitive even though there is a substantial chance that the antitrust litigation would vindicate the settlement *assuming* the parties' expectations about the litigation outcome are correct. That is an important assumption, which brings us to our third key observation. The conclusion that the settlement is anticompetitive is driven by the parties' subjective perception. To put it another way, it is driven by the intent of the parties to achieve an anticompetitive effect through a net reverse payment. Under *Actavis*, it is not the outcome per se that results in condemnation. *Actavis* would bless the very same 100/0 split of the patent life if there were no net reverse payment. The intent of the parties to obtain an anticompetitive objective is reflected in the net payment.[93] Fourth, from the perspective of the *Actavis* dissent, the settlement is lawful but the consumers are worse off than the expected value of litigation.

Hypothetical 4: Pessimistic litigants split the patent life with no net reverse payment.

Suppose that both parties believe that they have a 30 percent chance of prevailing. Obviously, at least one of them is wrong but they do not know that because both parties will overstate the likelihood of their prevailing during settlement negotiations. The parties settle by splitting the patent life 50-50. The *Actavis* majority would approve this patent splitting settlement as no consideration changed hands. The *Actavis* dissent would approve of this settlement as well. Under merits analysis, if the brand's expectations are correct, there is a 70 percent chance that the settlement will be condemned in the follow on antitrust litigation (because the brand's expectation would be that the generic should be able to enter at the beginning of year 4 rather than year 6).

If the brand's expectations are correct, the consumers are harmed and the settlement is anticompetitive. The brand would have been willing to settle for three years of exclusivity. If the generic's expectations are correct, however, consumers benefit and the settlement is procompetitive: the generic expected that on average it would not be able to enter until year eight.

This hypothetical illustrates multiple flaws in *Actavis*. First, the majority relies on the subjective view of the brand manifested in a net reverse payment that provides the court with a red flag concerning the brand's intent. Second, the brand may not be correct. The subjective view of the generic ought to increase one's doubt about the correctness of the brand's expectations. Third, the absence of a net reverse payment does not assure a competitive outcome. From the brand's

[93] The FTC must see the reverse payment as something other than intent evidence because the FTC belittles the use of intent evidence in its *Wellbutrin* amicus brief, citing several of the cases regarding intent cited in note 7, *supra*. *See* Brief of the FTC as *Amicus Curiae* at 27 & n.12, *In re Wellbutrin Antitrust Litig.*, No. 15-3559, 15-3591, 15-3681 & 15-3682 (3d Cir. Mar. 11, 2016) [hereinafter *FTC* Wellbutrin *Brief*].

perspective, the outcome here is as anticompetitive as in cases where the brand does make a net reverse payment.

If the settlement is governed by merits analysis, there is a chance that consumers will obtain treble damages through an antitrust trial. There now seems to be a tradeoff not evident in our earlier hypotheticals between minimizing the costs of the administration of justice and achieving a beneficial result for consumers. Indeed, some might argue that approving the patent litigation settlement in this hypothetical is not administering justice at all. Of course, if the Hatch-Waxman litigants expected that the merits analysis would govern this settlement, they might not settle. From the brand's perspective, it is likely that the brand would lose the antitrust litigation.

Actavis relies on the subjective view of the brand, i.e., its intent. But the key learning here is that the *Actavis* Court was mistaken in thinking that a settlement without a net reverse payment means there was no anticompetitive intent and no anticompetitive outcome.[94] Here, consumers are better off with merits analysis. The *Actavis* majority could have incorporated merits analysis into its methodology by condemning net reverse payments, but in the absence of reverse payment, engaging in merits analysis. It did not do so.[95]

Hypothetical 5

Hypothetical 5a: The brand prevailed in a litigation challenging patent validity but settles a second challenge.

Hypothetical 5a and 5b explore the interplay between the right of the patent holder to exclude and antitrust analysis. In this hypothetical, the brand has prevailed in a previous patent challenge but is facing a second challenge to the validity of its patent. The brand was forced to litigate the first challenge because the generic was unduly optimistic. This time, the brand believes it is 90 percent likely to prevail again and it is able to settle by making a net reverse payment in return for the generic's exclusion for the life of the patent.

Under *Actavis*, the settlement likely violates the antitrust law. The result is driven by a new perspective on antitrust/IP interface. A patent holder's right to exclude can be trumped by antitrust considerations where a red flag suggests that consumers are losing a chance for more competition. It might not matter to the *Actavis* majority if the patent holder had vindicated its patent by a preponderance of the evidence in previous or subsequent litigations.[96]

This may be something different than characterizing the patent as a probabilistic property right.[97] A probabilistic right is a right to exclude, which is no stronger than the patent holder's

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[94] The Court stated if there was no net reverse payment (because the payment covered litigation expenses or was compensation for fair value for services), the parties would not have "sought or brought about the anticompetitive consequences we mentioned above." *Actavis*, 133 S. Ct. at 2236.

[95] *Id.* at 2237.

[96] *Id.* at 2245 (Roberts, C.J., dissenting).

[97] *See* Shapiro, *supra* note 19, *at* 395 (characterizing a patent as a "*probabilistic* property right") (emphasis in the original); Petition for Writ of Certiorari for Plaintiff-Appellee, *FTC v. Schering-Plough Corp.*, No. 05-273, 2005 WL 2105243, at *16 (Aug. 29, 2005) (adopting Shapiro's conception of patents as "probabilistic").

expectations of the litigation outcome. With probabilistic rights, antitrust does not trump patents; it is rather a perspective on the extent to which patents bestow a right to exclude. This does not seem to be what the *Actavis* Court had in mind. Rather, it was thinking that where there is a suspicious agreement, antitrust considerations may take precedence over the patent holder's right to exclude, or perhaps more precisely, the patent holder's right to exclude based on the preponderance of the evidence.

Hypothetical 5b: The settlement fails and the parties continue to litigate.

After *Actavis*, Hatch Waxman litigants resolve a dispute by a large net non-cash payment of $6 billion that kept the generic out of the market for the ten-year duration of the patent life. The parties did so based on the assumption that *Actavis* only outlaws cash payments. As in other hypotheticals, the brand had $9 billion at stake as its profits would drop from $10 billion over the next ten years to $1 billion were it to lose the patent litigation the next day. The settlement is not final because the parties include a provision that they would abandon the settlement and return to litigation if the FTC questioned the settlement. The parties take the settlement to the FTC, and the immediate staff response is that the $6 billion net non-cash payment is anticompetitive and unlawful.

The parties abandon the settlement before it is final and return to litigation. The generic now argues to the court that it should prevail in the patent litigation without any further litigation on the patent merits because the net reverse payment shows that it is probable that the brand would lose the litigation and that the payment provided a "workable surrogate for the patent's weakness,"[98] requiring no deep dive into the patent merits. If, after *Actavis*, probabilistic analysis were the coin of the patent realm, the court would accept this analysis. But if *Actavis* only speaks to the conditions where antitrust law trumps patent rights, the court will instruct the parties to litigate the patent merits.

Hypothetical 6: No alignment in expectations but risk aversion leads to settlements.

According to *Actavis*, a net reverse payment is "strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market."[99] This hypothetical explores whether this is necessarily the case where the brand is risk averse. Risk aversion is the "'canonical' model of

[98] *Actavis*, 133 S. Ct. at 2236–37.

[99] *Id*. at 2235.

individual choice behavior"[100] and is thought to underlie the decision making of most corporate managers.[101]

Suppose that both the litigants believe that they have a 60 percent chance of prevailing in the patent litigation. In the absence of risk aversion, there seems to be no way to settle by just splitting the patent life. If the brand is risk averse, however, it may be willing to give up some expected patent life to obtain a settlement that removes the risk of losing the patent entirely. It proposes a 50-50 split but the generic rejects that split because it believes, on average, it will do $100 million better in litigation by getting on the market one year earlier. The brand is unwilling to give the generic another year because that will cost the brand an additional $1 billion. So the parties cannot settle for a simple split of the patent life. The brand then proposes paying the generic $100 million in addition to the 50-50 split to compensate the generic for the year it is falling short of *its* expectations (but not the expectations of the brand).

For a risk-averse brand, both the sacrifice of a year and the payment could be akin to paying premiums on an insurance policy. The expected value of buying insurance is negative but the insured does it to avoid an unacceptable risk.[102] So we can readily see that a net reverse payment does not necessarily result in an anticompetitive settlement from the brand's perspective if risk aversion is a factor driving the settlement and the parties are not aligned in their patent litigation expectations.

As far as consumers are concerned, they are better off than where they would be *on average* if the brand's expectation about litigation were correct (paying $6 billion over 10 years instead of $6.8 billion). But they are worse off than the generic's expectation of the outcome.

Table 1

	Settlement Hypothetical	Brand Expectation	Generic Expectation
Brand Revenues	$5.5 billion (less $100 million payment to generic)	$6.4 billion	$4.6 billion
Generic Revenues	$500 billion (plus $100 million payment from brand)	$400 million	$600 million
Consumer Payments	$6 billion	$6.8 billion	$5.2 billion

[100] Alvin E. Roth, *Comments on Tversky's Rational Theory and Constructive Choice*, in The Rational Foundations of Economic Behavior 198-202 (Kenneth Arrow et al. eds. (1996). It is well-understood that attitudes toward risk, whether traditional risk-aversion or the "loss-aversion" hypothesis from behavioral economics that can be linked to the Friedman-Savage non-convex utility hypothesis matter. Results that arise from modeling without uncertainty or by assuming strict risk-neutrality do not carry over when uncertainty and risk-aversion is present. *See* J.J. McCall, *Probabilistic Microeconomics*, 2 Bell J. of Econ. 404, nt. 4 (1971) and references cited therein.

[101] F.M. Scherer, *Industrial Market Structure and Economic Performance* 30 (2d ed. 1980).

[102] Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 Antitrust L. J. 1033, 1060-63 (2004); Barry C. Harris et al., *Activating Actavis: A More Complete Story*, 28 Antitrust, No. 2, 83, 85-87 (2014).

This agreement would be condemned under *Actavis* if *Actavis* does not permit the brand to rebut the presumption that a net reverse payment is anticompetitive. There is some language in *Actavis* that could be interpreted as precluding taking risk profiles into account. The Court said that a net reverse payment "likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm."[103]

But we have already established that *Actavis* permits the elimination of risk so long as the settlement contains no reverse payment. Thus we concluded in our discussion of Hypothetical 1, the economic objective of *Actavis* is not to prohibit the elimination of risk, but to eliminate adverse effects on the average consumer. So if economic effects are more important than formalistic line drawing, lower courts would consider the role of risk aversion in motivating the net reverse payment.

But if we take the Court literally, *Actavis* prohibits a reverse payment animated solely by risk aversion; it would condemn this settlement even though it seems to have exactly the same benefits as settlements that *Actavis* would approve, such as hypothetical 1.[104]

If merits analysis governed, both parties might conclude that this hypothetical is too close a call to settle the Hatch-Waxman litigation. The parties would continue the patent litigation just as they would under *Actavis*. Whether consumers are better off with the settlement depends on which party's expectation is more correct. But it is no small thing that consumers are doing better than the brand's expectations if the brand were permitted to make the net reverse payment.

The key learning here is that there may be occasions where a net reverse payment will achieve a more favorable outcome for consumers than the brand's patent litigation expectation.

Hypothetical 7

Hypothetical 7a: Efficiencies.

Both the brand and the generic believe that the brand has a 90 percent chance of prevailing. The brand pays net consideration to the generic to retain the entire patent life. In the antitrust litigation that follows, the brand contends that generic entry would reduce compliance with the drug's recommended dosage regimen and that the drug's output would fall. In the *Actavis* sense, there is an anticompetitive effect: there is a chance the drug's prices would be higher at some point because of the settlement. Given these claims, the jury needs to decide whether there is a

[103] *Actavis*, 133 S. Ct. at 2236. The Court also said that there is a "concern" that a reverse payment is the use of the brand's "monopoly profits to avoid the risk of patent invalidation or a finding of non-infringement." *Id*.

[104] We can change the hypothetical so that the generic is obtaining its expectation and only the brand is sacrificing in terms of time on the market and money. For example, the brand could believe it has a 50 percent chance of prevailing and the generic a 60 percent chance of prevailing. The brand offers the generic 60 percent plus money because of its risk aversion. The brand may be able to settle without the payment of money unless the generic is risk seeking or simply a good negotiator.

Providing the antitrust plaintiff with a non-rebuttable presumption of risk-neutrality allows the plaintiff to rely on a model that is not general and potentially not correct insofar as risk is concerned. However, requiring the plaintiff to demonstrate the risk profile of specific defendants is also problematic. One plausible allocation of proof would be to provide the plaintiff with a rebuttable presumption of risk neutrality.

net anticompetitive effect after balancing the anticompetitive effect and the compliance effect. The jury concludes that there is only a 40 percent chance that generic entry will reduce compliance to the point where output falls (holding the drug's price constant). Hence, it finds that the efficiencies are unlikely.

The problem is that it is also unlikely that the settlement resulted in less competition than in the but-for world. Indeed, there is only a ten percent chance of less competition, but the jury does not know this because the only evidence on point is the net reverse payment. In the absence of a patent trial within the antitrust trial, how is the court to determine whether the chance of efficiencies outweighs the chance of anticompetitive effects?

Hypothetical 7b: Efficiencies.

This hypothetical is similar to 7a but the brand and the generic believe that there is only a 30 percent chance that the brand would have prevailed in the patent litigation. The jury concluded that it is likely that generic entry will reduce compliance to the point where output falls. Again, the jury does not know there is a 70 percent chance that prices will be higher than they would have been in the but-for world. How is the court to determine whether the chance of efficiencies outweighs the chance of anticompetitive effects if they have not quantified the chance of anticompetitive effects?

Some Conclusions Derived from the Hypotheticals

Without legal limitations, there will be anticompetitive Hatch-Waxman settlements.

Our first conclusion, given the *Actavis* implicit definition of "anticompetitive," is that without some limitation, Hatch-Waxman settlements will often generate anticompetitive results. If the brand is making monopoly profits that generic entry would dissipate, the brand would be willing to use some of those profits to bribe the generic to stay off the market. The brand can offer the generic more in a bribe than the generic can make by entering the market. This is the result of the asymmetry between monopoly profits enjoyed by the brand and profits obtained through competition between the brand and generic. In fact, Hatch Waxman may render the asymmetry between the brand and the first generic unusually large. The first generic only has 180 days of generic exclusivity after which other generics can enter and compete. As we further discuss below, the generic may not even get that if the brand launches an authorized generic before the 180 day exclusivity period.

The methodology of the *Actavis* dissent, with the fewest limitations on settlements, will lead to the most anticompetitive outcomes.

Actavis abandons the preponderance-of-the-evidence standard for determining anticompetitive effects.

Consider Hatch-Waxman litigation where the brand believes it has a 60 percent chance of prevailing. It makes a reverse payment to the generic in return for 100 percent of the ten years remaining on the patent life. Consumers appear to be harmed because they are missing out on the

40 percent chance of competition. In a merits analysis, the payment is not central to the outcome and the antitrust jury would find no antitrust violation in six out of ten such antitrust litigations because, in those cases, the jury would find the brand has a patent that excludes the generic and there is consequently no anticompetitive effect outside the scope of the patent. In four out of ten such litigations, the jury would find an anticompetitive effect. That is, the jury would find by a preponderance of the evidence competitive in harm in the actual world as compared to the but-for world in four out of ten cases and would not find by a preponderance of the evidence competitive harm in the actual world in six out of ten cases. *Actavis* abandons the preponderance-of-the-evidence standard for determining the anticompetitive effect. The *Actavis* standard would outright prohibit a net payment that resulted in the brand obtaining 100 percent of the remaining patent life.

Technically, this is not the elimination of the preponderance standard, as the net reverse payment must be established by the preponderance of the evidence. But as a practical matter, the radical change in the evidentiary standard means that courts will condemn conduct that is not likely to have an anticompetitive effect when comparing the but-for world to the actual world. In the actual world, the brand obtained 100 percent of the patent life. In the but-for world, it was more likely than not that the brand would obtain 100 percent of the patent life (assuming the brand's expectation about the outcome of litigation was correct).

In *Actavis,* Justice Breyer and Chief Justice Roberts engaged in a debate about the relationship between antitrust and patent law. Chief Justice Roberts argued there can be no antitrust violation if the patent holder was operating within the potential scope of the patent.[105] Justice Breyer argued that a patent owner can violate the antitrust laws even if it acted within the potential scope. It "would be incongruous," according to Justice Breyer, "to determine antitrust legality by measuring [a] settlement's anticompetitive effect solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well."[106] "Yes," Justice Breyer could have said, "you might have established that you had a valid and infringed patent if you had pursued the patent litigation. But you only thought you had a 60 percent chance of prevailing in that litigation. Under the antitrust laws, your expectation about the litigation limits your right to exclude to 60 percent of the patent term."

If this interpretation is the correct one, it might limit the application of *Actavis* to the antitrust/IP interface. *Actavis* may not apply to seemingly identical economic outcomes where no patent is at stake. An even more narrow reading of *Actavis* is that it only applies to Hatch Waxman settlements: Congress created the potential for anticompetitive settlements under Hatch Waxman and some solution had to be found to prevent such anticompetitive settlements. We will be exploring these issues further.

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[105] Patent law "provides an exception to antitrust law, and the scope of the patent—*i.e.*, the rights conferred by the patent—forms the zone within which the patent holder may operate without facing antitrust liability." *Actavis*, 133 S. Ct at 2238 (Roberts, C.J., dissenting). However, the dissent does not reveal how a court should go about judging whether the generic's drug is within the potential scope of the patent if the issue is infringement rather than invalidity. How, under such circumstances, is the patent litigation different from the antitrust litigation in determining whether the alleged infringer's invention is within the scope of the patent?

[106] *Id.* at 2231.

Is it possible to view the *Actavis* methodology as something other than changing the evidentiary standard? The *Actavis* Court told us that a Hatch Waxman settlement should be judged under the rule of reason. Under that rule, an agreement should not be condemned unless it is actually anticompetitive. So this would seem to be an evidentiary issue and the Court appears to have changed the evidentiary standard. The Court, however, did suggest some short cuts in the analysis, prompting some to think that the Court was actually proposing a truncated rule of reason analysis despite language in the opinion to the contrary.[107] This would not appear to dispose of the evidentiary issue as the courts do not invoke truncation unless "an observer with even a rudimentary understanding of economics could conclude that the arrangement in question would have an anticompetitive effect."[108] The Court specifically stated that Hatch Waxman settlements did not satisfy this criterion.[109] So the Court seemingly was not trying to avoid analyzing the evidence to determine whether the conduct caused an anticompetitive effect.[110] It appears that *Actavis* is telling us that the courts may very well condemn a reverse payment even if *in a particular case* the competitive outcome, as reflected by a preponderance of the evidence, would be no more adverse in the actual world than in the but-for world.

Can we nevertheless characterize this as a policy choice rather than a change in the evidentiary standard? The policy is that conduct that increases the chances of an anticompetitive outcome (not offset by procompetitive effects), should be condemned even if it is not likely to have an adverse effect in a particular case, e.g., as described above, there is no anticompetitive effect in six out of 10 cases. While there may be no difference in outcome on average between the preponderance of the evidence standard and the *Actavis* standard, there is a difference in individual cases. Is it possible that as a matter of policy the Court is instructing the lower courts to ignore case specific outcomes? Perhaps, as a matter of policy, *Actavis* is telling us the difference in policy is simply applying the average outcome to all cases. It is not that antitrust plaintiffs get no damages in six out of ten cases and ten years' worth of damages in four out of ten cases. Instead, plaintiffs get four years' worth of damages in all cases.

A variation on this analysis is that the Court simply redefined what "anticompetitive" means as a matter of policy: henceforth, the courts will characterize any conduct that increases the chances of an adverse effect as "anticompetitive," rather than requiring in each individual case a preponderance of the evidence of more competitive harm in the actual world than in the but-for world. We will address further below whether treating the chance of an anticompetitive effect as a policy or evidentiary issue matters.

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[107] *See* Robert A. Skitol et al., *FTC v. Actavis: Inviting a More Nimble Rule of Reason*, 28 Antitrust, No. 1, 51-57 (2013).

[108] *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999).

[109] *Actavis*, 133 S. Ct. at 2237.

[110] There might be more in favor of analyzing the Court's holding as a policy preference rather than an evidentiary standard if *Actavis* had condemned the reverse payment per se. Then evidence of the anticompetitive effect would not have mattered, but that is not the path that the Court took. *See Palmer v. BRG of Georgia, Inc*.. 498 U.S. 48, 49-50 (1990) (holding market division agreement "unlawful on its face" even if the parties "merely reserve one market for one and another market for another.")

If the parties' expectations are correct, absent risk aversion, *on average,* consumers are often no better off with the *Actavis* solution than with merits analysis.

In a world without risk aversion, if the parties agree about the expected outcome of litigation and those expectations are correct, consumers, *on average*, may be no better off with the *Actavis* solution than with merits analysis. Returning to our example, where the brand believes it has a 60 percent chance of prevailing but makes a reverse payment in return for 100 percent of the patent life, as a result of the *Actavis* decision, consumers benefit from the 40 percent chance that the litigation will result in competition. If *Actavis* changes the litigants' behavior, consumers benefit in one of two ways. First, they may benefit because *Actavis* prohibits the reverse payment in most cases; therefore, the litigants might settle by splitting the patent life, e.g., 60-40, and consumers enjoy competition for 40 percent of the patent life. Second, if the litigants are unable to settle, the continued litigation gives consumers a 40 percent chance of competition for the entire remaining patent life. If *Actavis* does not change the litigants' behavior, consumers can seek antitrust damages equal to the competition during the 40 percent of the patent life that the consumers were denied, on average, because of the reverse payment.

Merits analysis results in antitrust litigation, which includes a patent trial within the antitrust trial. There is a 40 percent chance that the generic will prevail in the trial within a trial. Thus, there is a 40 percent chance that consumers will get damages equivalent to competition for ten years of the patent life and a 60 percent chance they will get no damages. Risk neutral consumers will be indifferent to the *Actavis* versus the merits results (excluding treble damages on the one hand and concerns that the damage award will actually get into the hands of the aggrieved consumers on the other hand). Over a large number of litigations, the average consumer is as well off through merits analysis as through *Actavis* analysis. The litigants and the court system benefit from *Actavis*, however, as it reduces litigation costs because there is no trial within a trial. Putting aside other flaws in *Actavis* methodology, this would seem to make the *Actavis* solution superior to the merits solution but only *if* the litigants' expectations about continued litigation are aligned and correct.

This analysis may not fully cover all real world situations. It may be true that, *prior to litigation,* consumers are no better or worse off using merits analysis than *Actavis* methodology. But after litigation, with merits analysis, the consumer either gets competition immediately or not at all. With *Actavis* analysis, the consumer gets some competition for part of the patent term most of the time.

There is an additional nuance if we suppose that the parties waive privilege and reveal their expectations about litigated outcomes.[111] Suppose the formerly privileged documents show that both parties thought it was 60 percent likely that the patent holder would prevail. The reverse payment resulted in the brand retaining 100 percent of the patent life. If there is no other

[111] Hovenkamp et al. urge courts to consider requiring the waiver of privilege if a party is defending an antitrust suit on the grounds that it would have prevailed in patent litigation but for the settlement. *Hovenkamp et al.*, *supra* note **Error! Unknown switch argument.**, § 7.03[C], at 7-22 to 7-23. If this became the rule, it raises the possibility that parties would craft their heretofore privileged documents to generate evidence that would be useful in future litigation.

evidence on the likely outcome of the Hatch-Waxman litigation, *Actavis* and merits analysis yield different results. *Actavis* would condemn the settlement. Merits analysis would not—if merits analysis can rely on the parties' expectations—because it is more likely than not that the patent endows the brand with the right to exclude. Under these circumstances, consumers are better off with the *Actavis* methodology than with merits analysis. We call the analysis in this paragraph a "probability assessment."

Not accounting for risk profiles may harm consumers.

Things might go awry if the lower courts do not take risk profiles into account. As Hypothetical 6 demonstrated, there may be occasions where no settlement is possible without a net reverse payment. But the parties can settle using such a payment if risk aversion changes the brand's incentives. In some such cases, from the brand's perspective, consumers are better off with such a settlement than with continued litigation. Despite the net reverse payment, the competitive results can be superior to settlements that *Actavis* permits. Whether the lower courts will take risk profiles into account will depend on whether they are more faithful to the *Actavis* language or to its underlying economic objective.

As already noted, under merits analysis, the payment and the risk profiles that generated the payment are not central to the analysis. The issue for the antitrust trial would be whether the patent is valid and infringed. Since this is the same issue as in the Hatch-Waxman litigation, the parties may decide to battle it out in the Hatch-Waxman context rather than the antitrust context.

Actavis relies on intent evidence.

While we have seen that a reverse payment does not necessarily reveal the brand's intent (because, for example, the payment may reflect risk aversion), it is still *Actavis*'s desideratum. The brand may think the net reverse payment is achieving a better result than the expected value of litigation, but the brand can be wrong.

Actavis relies on the intent of the brand, not necessarily the generic.

The net reverse payment does not tell us anything about the generic's intent. The brand's and the generic's expectations about the outcome of litigation do not necessarily align. In the absence of the *Actavis* decision, the generic would accept the net reverse payment even if it thought it was doing better by settling than by litigating. Of course, given the decision, the generic would have to turn down the net payment when it accepts the patent split even if it thought the split offers consumers a better outcome than litigating.

If the parties' expectations are not correct, the *Actavis* solution may make consumers worse off than merits analysis.

Under *Actavis* the brand's expectations about the patent litigation determine the antitrust outcome if those expectations are manifested in a net reverse payment. But no one has ever demonstrated that the brand's expectations are invariably correct. Nor has there been any study of the extent of alignment between the brand's and the generic's expectation. Nevertheless, under *Actavis*, the settling parties may not have the opportunity to litigate the patent claim to rebut the presumption that intent of just one of the parties demonstrates anticompetitive

effects.[112] An entire body of law now appears to depend on the anticompetitive intent of one of two settling parties. Imagine the chagrin of the generic that is offered a net reverse payment that would also result in it getting a bigger share of the patent life than it expects it would achieve though litigation. The saving grace here is that it can accept the split of the patent life, while turning down the net reverse payment.

This is not in keeping with merits antitrust analysis, where effects matter more than a single party's intent.

> Even in a settlement without a net reverse payment, one of the parties may intend to achieve an anticompetitive effect.

The *Actavis* majority is wrong if it thinks that absence of a reverse payment shows no anticompetitive intent. In Hypothetical 4, both parties expected they had a 30 percent likelihood of prevailing, but they settled for a 50-50 split with no net reverse payment. This was anticompetitive from the perspective of one of the litigants but has the *Actavis* stamp of approval.

> *Actavis* circumvents other elements of conventional antitrust analysis.

The decision also seems to eschew other facets of conventional antitrust analysis. Before *Actavis,* a full rule of reason analysis would require evidence of the anticompetitive effect, either actual detrimental effects or market power analysis that implies that there are such effects. The *Actavis* Court endorsed a full rule of reason analysis but found shortcuts. The intent of one party is sufficient to establish market power *and* adverse effects.[113] The Court in *Actavis* said that a departure from the rule of reason is only appropriate where "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."[114] The Court did not believe that a settlement with a reverse payment met that criterion.[115] At the same time, the Court stated that there is a sliding scale in appraising reasonableness and left to the lower courts the structure of the rule of reason litigation.[116]

Under *Actavis*, plaintiffs may not have to define markets and show market power in those markets to meet its burden under the rule of reason.[117] The logic underlying this position is revealed in *In re Aggrenox Antirust Litig.* If the brand was not "able to charge supracompetitive prices," it "is not clear why [it] would have sued [under Hatch Waxman] to prevent entry" of the

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[112] *Actavis*, 133 S. Ct. at 2236 ("[I]t is normally not necessary to litigate the patent validity to answer the antitrust question.").

[113] *Id.* at 2236 ("the 'size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power'—namely, the power to charge prices higher than the competitive level.") (quoting 12 P. Areeda & H. Hovenkamp, Antitrust Law ¶ 2046, at 351 (3d ed. 2012)).

[114] *Actavis*, 133 S. Ct. at 2237 (quoting *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999)).

[115] *Id.*

[116] *Id*. at 2238-39.

[117] *Id*. at 2236.

generic.[118] *In re Cipro Cases I & II*, the court likewise concludes there is "a presumption of the patentee's market power" because "[l]ogically, a patentee would not pay others to stay out of the market unless it had sufficient market power to recoup its payments through supracompetitive pricing."[119]

There does seem to be some tension between the rationale offered by the courts in *Aggrenox* and *Cipro* and the Supreme Court's view that patents do not necessarily convey market power.[120] Before *Actavis*, few would have thought that every patent holder that claims infringement and asks for an injunction has market power. Nor would an exclusion payment by a competitor to a potential competitor have been dispositive of market power. Imagine one of several local ice cream parlors in a community paying a potential competitor to refrain from opening a parlor across the street. Rather than jumping to the conclusion that the ice cream parlor has market power, some might reason that the incumbent was willing to pay to avoid losing half its sales thereby jeopardizing its viability. One could likewise imagine instances where the brand is making just ordinary profits that would shrink with generic entry and there may be some exclusion payment that allowed the brand to retain larger (but ordinary) profits.

Perhaps the issue is the size of the payment. The Court did say that the consequences flowed only from "large" payments but offered no guidance on the meaning of "large."[121] It is doubtful that the ice parlor exclusion payment would be very large. Plausibly then, market power analysis could come in through the back door. The defendants in the reverse payment antitrust litigation might attempt to establish that the payment could not be large because the brand had no substantial market power.

We can also reverse the logic, as proposed by James Langenfeld: a small payment relative to the size of the market suggests that the brand has no substantial market power.[122] Langenfeld argues

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[118] *In re Aggrenox Antirust Litig.*, 94 F. Supp. 3d 224, 247 (D. Conn. 2015).

[119] *In re Cipro Cases I & II*, 348 P.3d 845, 861 (Cal. 2015). This approach potentially confuses monopoly power with competitive rents arising in a world where firms make investments with uncertain outcomes. Some investments succeed while others fail, but the return on the portfolio of investments is normal. Firms that can wait to see which investments succeed and which fail, and can then free-ride on the work done by the innovator, will rationally chose to offer generics of successful products. But that lowers the return on the portfolio of investments reducing incentives for private firms to invest initially. Think of an alternative, an initially fair lottery. Now impose a tax on winners (but no subsidy for losers). The initially fair lottery is now unfair—the total invested to play is less than the post-tax return to the winner(s). Each initially fair lottery ticket is now unfair in that buying it guarantees an expected loss rather than a zero return. *Actavis* assumes that the relevant level at which to judge "monopoly power" is at the ex-post success drug rather than either the firm's overall portfolio or the industry portfolio.

[120] *Ill. Tool*, 547 U.S. at 45-46. *See also Revised IP Guidelines*, *supra* note 6, at 4.

[121] *Actavis*, 133 S. Ct. at 2236. "Large" may mean large relative to the size of the market or the estimated size of the generic's likely profits from entry during the period it agrees to stay out of the market. Alternatively, large may mean large in comparison to litigation costs. *See, e.g.*, King Drug Co. v. Cephalon, Inc., 88 F. Supp. 3d 402, 416-17 (E.D. Pa. Jan. 28, 2015) (agreeing that "reverse payment is sufficiently large if it exceeds saved litigation costs and a reasonable jury could find that the payment was significant enough to induce a generic challenger to abandon its patent claim.").

[122] James Langenfeld, *Evaluating the Size of 'Reverse Payments' in Light of the Supreme Court's Decision in FTC v. Actavis*, Competition Policy Int'l Antitrust Chronicle, Dec. 30, 2013, *available at* https://www.competitionpolicyinternational.com/assets/Uploads/LangenfeldSEP-2.pdf. /.

that if the size of the payments is taken to be proof of market power, then the payment should be a significant percentage of revenue to be considered large. Otherwise, the payment does not provide evidence that the patent holder is pricing substantially above a competitive level, and more analysis would need to be done to show market power.

A problem with this approach is that the *Actavis* Court is using the reverse payment as evidence of two things: an attempt to obtain higher profits than expected through litigation and market power. As far as obtaining higher profits is concerned, it does not necessarily take a lot of money (relative to monopoly profits) to get more monopoly if the patent is strong. The *Actavis* majority noted there would be a problem even if the brand was using a reverse payment to move from 90 percent likelihood that it could exclude the generic to 100 percent certainty through a settlement with a reverse payment.[123] Moving from 90 percent to 100 percent is likely to require a much smaller reverse payment than moving from 10 percent to 100 percent. Thus, a payment that is small relative to the size of the market may mean that the payment produced a small increase in the duration of the monopoly from the brand's perspective *or* it may mean little market power is involved. Because it may mean that little market power is involved, courts might give defendants leeway to show that they do not have market power using conventional forms of market analysis.

A red flag is central to the *Actavis* methodology.

Hypothetical 5 highlights some of the problems in relying on intent evidence. The net reverse payment is a red flag indicative of a brand's subjective assessment of its chances of success, rather than relying on a court and jury deciding the outcome based on the merits of the claim. This form of reasoning is strongly supported by Edlin, Hemphill, Hovenkamp, and Shapiro, who explain that "correct antitrust analysis must be based on what was reasonably known to the parties about patent validity and infringement *at the time they entered into their settlement*."[124] This is the "best information" available to courts and "it would make no sense to evaluate such 'risk' after the patent has been found valid or invalid."[125] (As already mentioned, the red flag does not tell us anything about what is "known" to the generic.)

It also endorses a novel view about how courts should make decisions. In *The Circular Logic of Actavis*, Joshua B. Fishman describes the *Actavis* reliance on a net reverse payment as an example of the prediction theory of law, equating legal propositions with litigants' prediction about what courts will do.[126] Citing to Oliver Wendell Holmes, Fishman writes that prediction theory is about a "bad man" who values knowledge of the law only to the extent that it helps him predict the consequences of his action.[127] But citing to H.L.A. Hart's Concept of Law, Fishman argues that this cannot provide guidance to judges deciding cases.[128] "[I]t does not provide the court any guidance in deciding an infringement case once a patentee has exercised its right to

[123] *Actavis*, 133 S. Ct. at 2236.

[124] Aaron Edlin et al., *The Actavis Inference: Theory and Practice*, 67 Rutgers U. L. Rev. 585, 617 (2015) (emphasis in the original).

[125] *Id*. at 618.

[126] Fischman, *supra* note **Error! Unknown switch argument.**6, at 98, 132.

[127] *Id*. at 112.

[128] *Id*.

sue."[129] But here we see that H.L.A. Hart might be wrong. The *Actavis* Court has abdicated the duty to decide the merits of controversies and has turn it over to the expectations of "bad men" under some circumstances.

There is a "striking irony" in the premises underlying the *Actavis* Court's holding, according to Fishman. The decision "assumes that the parties are sophisticated enough to accurately predict the outcome of patent litigation but oblivious to the possibilities of antitrust liability."[130] As we will discuss further below, there are now several court decisions condemning no-AG agreements—where the brand agrees not to introduce its own generic during the 180-day exclusivity period. According to the courts, while these agreements do not involve money, they involve a net reverse payment that is unlawful under *Actavis*.[131] So these courts were willing to rely on the brand's assessment of its patent litigation prospects, as manifested by its net reverse payment. But the courts do not even pay lip service to the brand's other implicit assessment: that the no-AG agreement is not an antitrust violation. In fact, from one perspective, the subjective antitrust assessment ought to receive more attention than the subjective patent assessment. As we showed, the generic's assessment of the patent merits might not align with the brand's assessment. The generic might have thought that the settlement was procompetitive despite the net reverse payment. But, having settled, it is likely that the brand's and the generic's antitrust assessment are aligned as neither likely thought the settlement would result in liability and treble damages under the Sherman Act.

> There is no easy means of balancing efficiencies against anticompetitive effects using the *Actavis* methodology.

The problem is illustrated in Hypothetical 7a and 7b. The conventional approach to assessing efficiencies in a Section 1 restraint of trade case starts with the plaintiff satisfying the initial burden of proving an anticompetitive effect. The burden then shifts to the defendant to establish efficiencies. If the defendant does meet its burden, to prevail, the plaintiff must prove that the restraint is not necessary to achieve the efficiencies, that the efficiencies can be achieved in a less restrictive manner or that the anticompetitive effect outweighs the efficiencies.[132]

Weighing efficiencies against anticompetitive effects is very challenging even under conventional burdens of proof. *Actavis*'s shortcut methodology does not seem to lend itself to any form of balancing. As noted, if the proof of an anticompetitive effect flows from the net reverse payment, the jury would know little about the likelihood that there would be more competition in the but-for world than in the world with a settlement. The jury and the court would only know that there is a chance of greater competition without the settlement. It is hard to

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[129] *Id.* at 117.

[130] *Id.* at 98.

[131] The no-AG decisions are also interesting because generic drug producers have argued that authorized generics are a tool designed to exclude "legitimate" generics from the market by reducing the value of, among other things, the 180-day exclusivity period. The AG-issue is complicated by the fact that some third-party payers have refused to buy authorized generics or have refused to accept significant discounts on the branded product given around the time of generic entry. For a commentary along this line, *see* Beth Understahl, *Authorized Generics: Careful Balance Undone*, 16 Fordham Intell. Prop., Media & Ent. L. J. 356 (2005).

[132] *See, e.g.*, *United States v. Visa U.S.A, Inc*., 344 F.3d 229, 238 (2d Cir. 2003);

see how that unquantified chance of competition could be balanced against a quantified chance of efficiencies.

Employing a conventional approach, the magnitude of likely efficiencies would be balanced against the magnitude of likely anticompetitive effects. Applying *Actavis* would require not only balancing magnitudes but also gradations of probability. Where the defendant is claiming settlement efficiencies, the court might permit the defendant to try the patent case inside the antitrust case. This would provide some evidence on the probability that the settlement stifled competition. This probability could then be balanced against the probability of some procompetitive efficiency. Of course, the comparison must include not only the probability of each phenomenon but the magnitude of each phenomenon.

Additional Unresolved *Actavis* Issues

Antitrust Injury

One issue not resolved by the *Actavis* Court is whether antitrust injury is judged using the same methodology that determines adverse effects. A private plaintiff in antitrust litigation must show antitrust injury. This is "injury of the type that the antitrust laws were intended to prevent and that flows from that which makes the defendants' acts unlawful."[133] The point is to assure "that a plaintiff can recover only if the loss stems from a competition-*reducing* aspect or effect of the defendant's behavior."[134] As already discussed, under *Actavis,* a reverse payment is competition-reducing because the settlement that results reduces the chance of competition for some period. In some of our hypotheticals, the competition-reducing aspect of the behavior is the loss of the 40 percent chance that customers would see more competition and lower prices as a result of the generic entering the market after prevailing in the Hatch-Waxman litigation. So, at first blush, one might think that a purchaser of the pharmaceutical at issue would suffer an antitrust injury if it lost the 40 percent chance of competition; it would be harmed and thereby suffer antitrust injury by the competition-*reducing* aspect of the settlement.

Several district courts have come to this conclusion. In *In re Opana ER Antitrust Litigation,*[135] the court held that "the anticompetitive harm is not that the patent surely would have been invalidated if not for the settlement, and that a generic therefore surely would have entered the market at an earlier date. If that were the standard, a determination of a patent settlement's lawfulness under antitrust law would require the very same patent litigation that the settlement avoided."[136] In *In re Aggrenox Antitrust Litigation*,[137] the court stated that "[i]f private antitrust plaintiffs must fully litigate the validity of the patent anyway in order to show but-for causation, then *Actavis'*s insistence that litigating the patent is not normally necessary to show that a large and unjustified reverse-payment settlement violated the antitrust law would have no practical

[133] *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334(1990).

[134] *Id.* at 344 (emphasis in the original).

[135] *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704 (N.D. Ill. 2016).

[136] *Id.* at 720.

[137] *In re Aggrenox Antitrust Litig.*, No. 3:15-md-2516, 2015 WL 4459607 (D. Conn. July 21, 2015).

effect in private suits, and *Actavis* itself therefore would have no practical application except in suits by the government."[138]

On the other hand, the first fully litigated post-*Actavis* court of appeals decision, *In Re: Nexium (Esomeprazole) Antitrust Litigation,*[139] deserves our attention, with the caveat that it might not be consequential given the plaintiffs' failure to properly object to the relevant jury instructions. Antitrust injury was at issue in the litigation. AstraZeneca was the manufacturer of Nexium, a heartburn drug. Ranbaxy and others filed ANDAs, along with paragraph-IV certifications, to compete with Nexium through generic formulations. AstraZeneca supposedly made net reverse payments to three generic manufacturers, including first-filer Ranbaxy. The settlement was reached in 2008. Under the Ranbaxy settlement, Ranbaxy agreed not to enter until May, 27, 2014.[140] In return, AstraZeneca agreed, among other things, not to market an authorized generic version of Nexium during Ranbaxy's 180-day exclusivity period (a no-AG agreement).[141]

To understand the outcome in the trial court, we reproduce two of the questions posed to the *Nexium* jury.

> 3. Was AstraZeneca's Nexium settlement with Ranbaxy unreasonably anticompetitive, i.e. did the anticompetitive effects of that settlement outw[ei]gh any pro-competitive justifications?[142]
>
> 4. Had it not been for the unreasonably anticompetitive settlement, would AstraZeneca have agreed with Ranbaxy that Ranbaxy might launch a generic version of Nexium before May 27, 2014?[143]

The jury answered "yes" to question 3, indicating that the settlement was anticompetitive. But the jury answered "no" to question 4. This ended the case in defendants' favor and prompted the appeal. According to the appeals court, question 3 was about whether the settlement was anticompetitive and the law was thereby violated and question 4 was about antitrust injury. Since there was no antitrust injury, plaintiffs had no standing.[144] The Court of Appeals does not explain why question 4 is a proper question to resolve the injury issue. Nor does the Federal Trade Commission in its amicus brief, which argued that there is a difference between a violation of antitrust law and antitrust injury, but which did not explain what the difference is in this particular case.[145]

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[138] *Id.* at *9.

[139] *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F. 3d 34, 39-40 (1st Cir. 2016) (petitions for panel rehearing and rehearing en banc denied January 10, 2017).

[140] Ranbaxy could launch earlier if a third party launched generic Nexium pursuant to a final, nonappealable court order that AstraZeneca's Nexium patents were invalid, unenforceable, or not infringed by the generic. *Id* at 42.

[141] *Id*. at 42.

[142] *Id*. at 50.

[143] *Id*.

[144] *Id*. at 60.

[145] *See generally* FTC *Wellbutrin* Brief, *supra* note **Error! Unknown switch argument.**.

The "yes" answer to question 3 means that the reverse payment reduced the chance of earlier competition that would have benefited buyers. How then is it possible that the plaintiffs, who are the buyers, suffered no injury as a result of the reduced competition? Question 4, according to the lower court's instruction to the jury, was necessary because "[j]ust making a deal … is not enough for liability[;] there has to be a harm."[146] So the jury then had to consider what would happen if the defendants "were settling straight up without any anticompetitive effects, would that settlement license entry data have been earlier than the date they agreed to, May 27th, 2014?"[147]

But if the parties would have agreed to the May 27, 2014 date without a net reverse payment, how could there have been an anticompetitive effect and a violation of law as revealed in the answer to Question 3? Of course, if there was an anticompetitive effect and a violation of law as revealed in Question 3, how is it possible that the plaintiffs were not injured by that anticompetitive effect? The plaintiffs are buyers of the drug in question. If there was an anticompetitive effect, it was because there was a chance that entry was delayed. If there was a chance that entry was delayed, it would seem that the plaintiffs were injured because they lost their chance at receiving the benefits of competition as a result of that earlier entry.

According to the court, the "no" answer to question 4 meant that the parties would not have negotiated an earlier entry date without the net reverse payment.[148] The court concluded that there was no contradiction between the answers because Question 3 was about violation of law and Question 4 was about antitrust injury.[149] The court properly noted that antitrust violation and antitrust injury are two different things, both of which a private plaintiff must establish.[150] But the court did not explain why Question 3 did not respond to both the antitrust violation and the antitrust injury questions.

The only way to reconcile these answers is that Question 3 and Question 4 were using different standards of proof. The answer to Question 3 was "yes" because there was a chance of reduced competition. But perhaps the jury (and the court of appeals) thought that question 4 demanded a "yes" or a "no" based on the preponderance of the evidence: was it more likely than not that Ranbaxy would have entered earlier but for the suspect settlement? This does not seem unreasonable given the general charge to civil juries on the preponderance of the evidence. If the special verdict form had followed *Actavis* thinking in evaluating injury, the question inquiring about antitrust injury might have been worded: "Had it not been for the settlement, was it *possible* that Ranbaxy would launch a generic version of Nexium before May 27, 2014?" But not all courts, as this case illustrates, are willing to make possibilities, rather than likelihoods, outcome determinative.

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[146] *Nexium*, at 50.

[147] *Id*.

[148] *Id*.

[149] *Id*. at 60.

[150] *Id.* at 60-61.

Because the plaintiff's did not properly object to question 4, the only issue for the court of appeals was whether there was plain error in the formulation of the question.[151] The error seems pretty plain *if Actavis* methodology applies to antitrust injury. The court's resolution opens the door to a suggestion that conventional analysis rather than the *Actavis* methodology applies to the standing issue.

If this became the rule of law, it would undo *Actavis* in private antitrust suits. There may be a violation of law but a private plaintiff has no standing unless it can prove that it is more likely than not that the generic would have entered sooner. A reverse payment does not prove that. The only means of proving that may be through a patent trial within the antitrust trial. This, of course, is not the case for the FTC, which does not need to establish antitrust injury. The FTC made this point in its amicus brief, essentially throwing private plaintiffs under the bus.[152]

Damages

Even if courts apply the *Actavis* methodology to antitrust injury, *Nexium* does make one wonder how the courts will grapple with damages. The first issue in the recovery of damages is injury in fact, without which a damages award is not possible.[153] Injury in fact must be shown with a "reasonable degree of certainty."[154] As noted in hypothetical 2, a payment demonstrates a violation under the *Actavis* methodology even if the brand is 90 percent likely to prevail in Hatch Waxman litigation. A ten percent chance that consumers would get more competition but for the

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[151] *Id*. at 59.

[152] Brief of the FTC as *Amicus Curiae* at 3-4, *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F. 3d 34 (1st Cir. 2016) [hereinafter *FTC* Nexium *Brief*]. The FTC takes a similar position in its *amicus* brief in *In re Wellbutrin*. *FTC* Wellbutrin *Brief*, *supra* note 91, at 19. The FTC brief implies that antitrust injury requires more evidence of injury than a settlement that reduced the chance of competition. The FTC first argues that all that is required to find a violation is a payment "to prevent the risk of competition" *Id*. at 18 (quoting *Actavis*, 133 U.S. at 2236). But then implies (but does not clearly state) that antitrust injury requires proof that the generic would have "actually launched in the absence of the settlement agreement." *Id*. at 19. There is no doubt that violations of the antitrust laws do not automatically confer standing, but the FTC does not explain why the plaintiffs, purchasers of the pharmaceutical in question, would not have standing where there is a chance that they could have been injured by the prevention of the risk of competition that constitutes the violation.

The FTC *amicus* brief does suggest that private law suits are important in the enforcement of the antitrust laws. In *Wellbutrin,* the settlement agreement keeping the generic off the market for a particular dosage of the drug in question for some time included a provision that if the FTC objected to the settlement, the parties would "either resolve the objection or have a right to terminate the entire agreement." *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 762 (E.D. Pa. 2015). The lower court noted that even "a note of concern" from the FTC "was sufficient to alter or terminate the settlement." *Id*. at 761. Yet the FTC raised no concern despite a meeting with agency personnel. *Id*. *See also FTC* Wellbutrin *Brief*, *supra* note **Error! Unknown switch argument.**, at 28 n.13. The FTC responded that government inaction does not indicate agency approval. *Id.* at 28-29 (citing *Altria Group, Inc. v. Good*, 555 U.S. 70, 89-90 (2008). The FTC further argued that "[c]ourts impute no legal significance to agency inaction" because "[a]n agency's exercise of its enforcement discretion 'involves a complicated balancing' of factors, including … whether the agency has available enforcement resources, and whether a potential action 'best fits the agency's overall policies.'" *Id*. at 29 (quoting *Heckler v. Chaney*, 470 U.S. 821, 831 (1985). *See also Moog Indus., Inc. v. FTC*, 355 U.S. 411, 413 (1958) ("the Commission alone is empowered to develop that enforcement policy best calculated to achieve" its statutory mission).

[153] *Story Parchment Co. v. Paterson Parchment Paper Co*., 282 U.S. 555, 563 (1931).

[154] *Mostly Media v. U.S. W. Commc'ns*, 186 F.3d 864, 865 (8th Cir. 1999).

settlement does not seem to meet the reasonable certainty standard. The courts will thus have to decide whether *Actavis* demands a relaxed standard for injury in fact, more in accord with the *Actavis* standard for a violation.

Even if *Actavis* augers a new standard for injury in fact, that does not tell us how to calculate actual damages. There is a looser standard for proving damages once injury in fact has been demonstrated.[155] The question is how loose of a standard does *Actavis* permit? Proponents of the *Actavis* methodology propose the following to assess damages:

> Individual plaintiffs will then prove damages by showing the time period during which competition was reduced by the settlement, the magnitude of price erosion caused by entry, and the extent of their purchases during the damages period.[156]

But what is the damages period? Returning to our hypothetical where the brand believes it has a 90 percent chance of prevailing but obtains exclusivity on the ten years of remaining patent life through a net reverse payment, one might conclude that the payment denied consumers one year of competition. While this seems to follow the *Actavis* methodology, we only know the 90 percent expectation by hypothesis. The jury is unlikely to know this and could only assess the specific probabilities of such outcomes by delving deeply into the merits of the patent litigation, more deeply than we would expect from a patent jury, which would only have to determine the outcome based on the more-likely-than-not standard. Using probabilities in this way would undo the simplification of the analysis that the *Actavis* Court was trying to provide.

Another approach might be to use the size of the reverse payment to determine the damages.[157] So, for example, assume the litigants all agree on the 90 percent expectation (although the jury does not know this). A jury could size the damages by converting the payment into a time period. Assume in our example that the brand is making $1 billion per year because of its patent and the lack of immediate competition. The generic would make a profit of $100 million per year upon entry. The brand pays $100 million to keep the generic off the market until the patent expired. This payment suggests that entry was delayed by one year. Damages to consumers could be calculated based on the projected magnitude of the price erosion and the projected volume of purchases by plaintiffs during that year.

But the reverse payments in our hypotheticals are driven by the brand's expectations, subject to at least satisfying the generic's expectations through time or money. To see the weakness in our damages analysis, assume that parties both have a 90 percent expectation that the brand will prevail but the parties are not aware of each other's expectation. The brand would be willing to offer between $100 million and almost $1 billion to keep the generic out of the market for the life of the patent. Assume that the generic is a good bluffer and the brand believes it will have to offer more than $100 million to exclude the generic for the life of the patent. The brand might offer $500 million and the generic would happily accept. Despite the fact that the parties actually

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[155] *Zenith Radio Corp. v. Hazeltine Research*, 395 U.S. 100, 123-24 (1969).

[156] *Edlin et al*., *supra* note **Error! Unknown switch argument.**, at 20 (2013).

[157] *See id*. at nt. 52. Using the size of the payment seems inconsistent with the authors' perspective in a later paper, where they opine, "*Actavis* never states that the value of the payment must be ascertained, but only that it must be shown to be above reasonably anticipated litigation costs." *Edlin, et al., supra* note 119 at 601.

agree (though they do not know it) that the expected outcome is one year of competition before patent expiration, the suggested damages methodology would wrongly assume that the generic would enter at the beginning of year six but for the settlement.

Suppose the litigants do not agree. The brand believes it has a 90 percent chance of prevailing and the generic believes it has a 100 percent chance of losing. The settlement could still be at the $500 million level if the generic is a good bluffer. Again, the reverse payment tells us little about the period of exclusivity that the brand purchased.

Thus we can see that the size of a net reverse payment does not tell us enough about the extent of the delay. There are two reasons. First, there is a difference between the values of time to the litigants. And, we do not know whose value the net reverse payment reflects. Second, the generic through sophisticated bargaining tactics may obtain a better settlement than it expects to obtain in litigation (although in the absence of risk aversion it cannot obtain a better settlement than the brand's expectation). Indeed, if litigation is the alternative outcome, a settlement must be at least as good for the generic as litigation given the generic's expectations; it cannot be worse. Similarly, the outcome from settlement must be at least as good as litigation from the perspective of the brand; it cannot be worse. If it were, then litigation would continue.

All we know as a result of a $500 million payment is that from the brand's subjective perspective, assuming no risk aversion, the payment delays entry between one half year and five years (assuming the brand's expectations are correct). To do better, the court would have to delve deeply into the merits of the patent litigation.

Of course, even if defendants are barred from offering risk aversion as a counter to a violation, that does not necessarily mean that they could not offer risk aversion as a counter to damages, arguing the reverse payment reflects risk aversion rather than any delay in entry. If such were the case, the net reverse payment alone would not provide any insight into damages.

It seems that there is no satisfactory solution to the damages issue other than requiring exactly what *Actavis* attempted to avoid—a patent trial within an antitrust trial. And, to remain true to the *Actavis* reasoning, even that requires the jury to render a probabilistic conclusion that seems beyond its capability.

We can also ask the same question here that we ask in other contexts. Why stop with altering damages calculations for reverse payments? Consider for example a market division case, where the allegation is that the defendants agreed they would not enter each other's markets. Everyone agrees that they are not *likely* to enter but there is a chance they would have entered but for the agreement. This is a violation under *Actavis* methodology and the damages should relate somehow to the probability of entry.[158] We may be on quite a slippery slope.

[158] Long before *Actavis*, in *Palmer*, 498 U.S. at 49, the Court held that market divisions among potential competitors could be unlawful.

The Slippery Slope of Mt. *Actavis*

The No-AG Agreement

A brand can repackage its FDA-approved drug as a generic and market it at any time. This means that the brand can compete with the first-filer generic during its 180-day "exclusivity" period.[159] Because the first 180 days are extremely valuable to the first filer generic,[160] the brand's competition in that period through its own authorized generic threatens the generic's profitability.[161] So a Hatch Waxman settlement under which the brand promises not to compete with an authorized generic (the no-AG agreement) can be valuable to the generic as we already saw in the discussion of *Nexium*.

Two appeals courts have rendered decision on whether a no-AG agreement amount to a reverse payment and both have concluded that it does. In *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp*.,[162] the court concluded that "no-AG agreement falls under *Actavis'*s rule because it may represent an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of competition."[163] It reasoned the no-AG agreements "present the same types of problems as reverse payments of cash."[164] The court rejected the argument that a no-AG agreement constituted an exclusive license permitted by patent law because the conduct amounted to more than just an exclusive license; it amounted to the use of the license "to induce a patent challenger's delay."[165]

The First Circuit in *In re Loestrin Antitrust Litigation*[166] came to the same conclusion. It reversed a district court opinion that had held that *Actavis* "fixates on one form of consideration that was at issue in the case: cash."[167]

The appeals court rejected this analysis, concluding that the district court "overstates" the Supreme Court's emphasis on cash. The Supreme Court, according to the court of appeals, includes any of the forms of "reverse payment that induce the generic to abandon the patent

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[159] *Teva Pharm. Indus. v. Crawford*, 410 F.3d 51, 55 (D.C. Cir. 2005).

[160] *Actavis*, 133 S. Ct. at 2229.

[161] According to an FTC report, the first-filer generic can lose about half of its profits as a result of generic competition from the brand. FTC, Authorized Generics: An Interim Report 57-59 (2009), *available at* https://www.ftc.gov/sites/default/files/documents/reports/authorized-generics-interim-report-federal-trade-commission/p062105authorizedgenericsreport.pdf.

[162] *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp*., 791 F.3d 388 (3d Cir. 2015).

[163] *Id*. at 394. This assumes that a credible threat to launch an authorized generic (or generics) just prior to alleged infringer entry and during the 180-day exclusivity period would not cause the generic filer to rethink its decision to enter. Authorized generics may also induce some ANDA IV filers to enter "at risk" or threaten to do so.

[164] *Id*. at 404.

[165] *Id*. at 406.

[166] *In re Loestrin 24 FE Antitrust Litig.*, 814 F.3d 538 (1st Cir. 2016).

[167] *In re Loestrin 24 FE Antitrust Litig.*, 45 F. Supp 3d 180, 189 (D.R.I. 2014), *vacated* 814 F.3d 538 (1st Cir. 2016).

challenge, which unreasonably eliminates competition at the expense of consumers."[168] The court also reasoned that allowing non-cash reverse payments would give "manufacturers carte blanche to negotiated anticompetitive settlements."[169]

Ten district courts have also agreed that no-AG agreements can amount to net reverse payments condemned by *Actavis*.[170] Two district courts have been more cautious about non-cash payments, requiring some level of precision on the monetary value of the non-cash payment.[171] Other courts have not required as much precision, particularly at the pleading stage.[172]

Many commentators concur that the no-AG agreements are unlawful. They reason that there is no difference between a cash payment and a no-AG agreement or any other non-cash consideration. They all constitute a bribe to extend the brand's monopoly beyond the brand's expectation of the litigation outcome. For example, according to Edlin, Hemphill, Hovenkamp and Shapiro limiting *Actavis* to cash payments would "open up a gaping loophole."[173] According to Michael Carrier, the question of a cash reverse payment is equivalent to a no-AG agreement is "embarrassingly easy."[174] He offers eight reasons for this easy conclusion. All of these reasons

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[168] *Loestrin*, 814 F.3d at 549-50.

[169] *Id*. at 550.

[170] *Hovenkamp et al.*, *supra* note **Error! Unknown switch argument.**, § 16.01[D], at 16-39 & n.149.

[171] In *In re Effexor Antitrust Litig.*, No. 11-5479, 2014 WL 4988410, at *19 (D.N.J. Oct. 6, 2014), the court held that a non-cash payment must be "converted to a concrete, tangible or defined amount which yields a reliable estimate of a monetary payment." The same conclusion was reached by the court in *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523, 543 (D.N.J. 2014).

[172] *See United Foods & Commercial Works Local 1776 v. Teikoku Pharma USA, Inc. (Lidoderm),* 74 F. Supp 3d 1052, 1070 (N.D. Cal. 2014) (the transfer of product encouraging settlement "is not a complex, multifaceted payment" requiring precise calculation); *Aggrenox*, 94 F. Supp. at 244 (precise estimates of the reverse payment require discovery); *Loestrin*, 814 F.3d at 552; *In re Opana ER Antitrust Litig*., 162 F. Supp. 3d at 718 (sufficient to plead a range of values for the no-AG agreement); *In re Solodyn Antitrust Litig*., No. 14-md-02503-DJC, 2015 WL 5458570, at *7 (D. Mass. Sept. 16, 2015) (motion to dismiss denied where the reverse payment was reflected in upfront and milestone payments).

[173] Edlin et al., *supra* note **Error! Unknown switch argument.** at 592. *See also* Joshua P. Davis & Ryan J. McEwan, *Deactivating Actavis: The Clash between the Supreme Court and (Some) Lower Courts*, 67 Rutgers U. L. Rev. 557, 559 (2015) ("[L]imiting Actavis to cash could render it a dead letter" because "there is no meaningful distinction between the effect of a cash payment and a non-cash payment…."). Former FTC Commissioner Joshua Wright has concluded that this call is "not even a close one." Joshua Wright, Address at the Antitrust Masters Course VII: Antitrust Analysis of Reverse Payment Settlements after Actavis: Three Questions and Proposed Answers 5 (Oct. 10, 2014), https://www.ftc.gov/system/files/documents/public_statements/591131/141010actavisspeech.pdf. Former FTC Chairwoman Edith Ramirez stated that the FTC is committed "stopping pay-for-delay agreements that inflate the prices of prescription drugs and harm competition, regardless of the form they take." Press Release, FTC, FTC Sues Endo Pharmaceuticals Inc. and Others for Illegally Blocking Lower-Cost Generic Versions of the Branded Drugs Opana ER and Lidoderm (Mar. 31, 2016), https://www.ftc.gov/news-events/press-releases/2016/03/ftc-sues-endo-pharmaceuticals-inc-others-illegally-blocking-lower. Following through on this commitment, the FTC has submitted several amicus briefs making the same point. *E.g.*, Brief of the FTC as *Amicus Curiae*, Am. Sales Co. v. Warner-Chilcott Co., Nos. 14-2071 & 15-1250, *19 (1st Cir. June 16, 2015).

[174] Michael A. Carrier, *Forward: After Actavis: Seven Ways Forward*, 67 Rutgers U. L. REV. 549 (2015).

are related to the fact that the Supreme Court requires antitrust analysis to "be based upon demonstrable economic effects rather than … formalistic line drawing."[175]

To explore this further, we start with the article by this author cited in both the *Actavis* majority and dissent, Schildkraut, Patent-Splitting Settlements and the Reverse Payment Fallacy. That article demonstrated that there is no economic difference between net reverse payments in the Hatch-Waxman context and the compromise of damages to settle more traditional patent cases.[176]

In the traditional case, the alleged infringer is already competing, sometimes resulting in settlements where the infringer agrees to end or limit its competition and the patent holder takes less in damages than it expects through litigation. The patent holder reaches this settlement because it removes the risk that it would lose the litigation and lose its monopoly for the remainder of the patent life. To put it in the same terms as the hypotheticals above, the patent holder that believes it has 90 percent chance of prevailing in the patent litigation pays to secure 100 percent of the patent life by accepting reduced damages.[177] From the patent holder's perspective, we have an iconic exclusion payment where the patent holder is getting more monopoly than it expects to get through litigation.[178] The alleged infringer settled on terms that were more favorable than the infringer's expected outcome of continued litigation. By settling, the infringer avoided the chance of a damage award equal to the monopoly profits the patent holder lost due to the ongoing competition with the alleged infringer. Thus, it is in the interest of both parties to settle, the patent holder, because it gets more monopoly than expected and, the

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[175] Michael Carrier, *Eight Reasons Why "No-Authorized-Generic" Promises Constitute Payment*, 67 Rutgers U. L. REV. 697, 715 (2015) (quoting *Sylvania*, 433 U.S. at 58-59). The eight reasons are 1) the *Actavis* Court's phraseology encompasses payments extending beyond naked cash payments; 2) the payments at issue in *Actavis* were actually overpayments for generic services rather than a naked cash payment; 3) the no-AG agreement provides significant value to generics; 4) the value of the no-AG agreements to the generic can be larger than winning the litigation; 5) the brand acts against its self-interest in making the no-AG pledge; 6) treating the no-AG agreement as something other than a reverse payment would emphasize form over substance; 7) AGs can undermine the value of the 180-day exclusivity period, making the no-AG agreement more valuable than a cash payment; 8) the no-AG agreement is a market division agreement. *Id.* at 705-720.

[176] Schildkraut, *supra* note 101, at 1046-1049.

[177] In some cases, the alleged infringer will not be in a unique position to challenge the patent's validity. So a settlement with one party would not prevent others from challenging validity. On the other hand, if the alleged infringer had invented a patent work around, there may not be others able to challenge the patent. This presents the question of whether a settlement between the patent holder and the alleged infringer is less likely to be anticompetitive when the central issue in dispute is validity. Under some circumstances, the patent holder may not be able to achieve an exclusionary objective where there are many others that could challenge the validity of the patent. There may be other circumstances, however, where an exclusionary objective can be achieved even if validity is the only issue in the patent litigation. The alleged infringer may have to overcome substantial entry barriers other than the patent and establish a position in the market that others could not readily duplicate. Bribing the alleged infringer out of the market with a compromise of damages can consequently result in anticompetitive prices until others have overcome these entry barriers.

[178] See numerical example in Schildkraut, *supra* note 101, at 1046-47.

alleged infringer, because it pays lower damages than expected. The *Actavis* dissent well understood this.[179] The majority understood this as well:

> [W]hen Company A sues Company B for patent infringement and demands, say, $100 million in damages, it is not uncommon for B (the defendant) to pay A (the plaintiff) some amount less than the full demand as part of the settlement—$40 million, for example. See Schildkraut, Patent-Splitting Settlements and the Reverse Payment Fallacy, 71 Antitrust L. J. 1033,1046 (2004) (suggesting that this hypothetical settlement includes "an implicit net payment" from A to B of $60 million—*i.e.,* the amount of the settlement discount).[180]

The majority then indicates that it does "not intend to alter that understanding" that such settlements are lawful.[181] The Court does not cite to precedents that established this understanding (and this understanding does not comport with merits analysis). Nevertheless, according to the majority, "walk[ing] away with *money* . . . is something quite different."[182] The majority does not explain how walking away with money is different from walking away with a discount on expected damages. Nor do the lower courts addressing the no-AG settlements explain why a compromise of damages is different from a no-AG agreement. To put the *King Drug* court's words into this context, a compromise of damages "present the same types of problems as reverse payments of cash."[183] It does not seem that the Supreme Court's distinction between the two forms of settlement is "based upon demonstrable economic effects."[184]

The *Actavis* Court offered one other distinction. In the traditional settlement of a patent lawsuit, "a party with a claim (or counterclaim) for damages receives a sum equal to or less than the value of its claim."[185] There are two ways to interpret this thought and neither way is very satisfying. First, the compromise of damages is equal to or less than the value of its claim because the patent holder sought more in damages than it obtained in the settlement. This cannot be the correct interpretation because brands in the Hatch Waxman litigation seek an injunction that would keep the generic out of the market for the remaining life of the patent. If it paid to keep the generic out for less than the remaining life, it received less than the value of its claim. If it paid to keep the generic out for the life of the patent, it received the equal of the value of its claim. In other words, in both the compromise of damages and the reverse payment, the patent holder achieved less than or the same amount that sought to achieve when it filed the lawsuit.

Another interpretation is that the patent holder is receiving the equivalent of or less than its subjective view of the value of what it claimed. But this cannot be correct either. First, a risk

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[179] *Actavis*, 133 S. Ct. at 2243 (Roberts, C.J., dissenting).

[180] *Id.* at 2233.

[181] *Id.* ("Insofar as the dissent urges that settlements taking these commonplace forms have not been thought for that reason alone subject to antitrust liability, we agree, and do not intend to alter that understanding.")

[182] *Id*. (emphasis added).

[183] *King Drug*, 791 F.3d at 404.

[184] *See supra* note 167 and accompanying text.

[185] *Actavis*, at 2233.

neutral patent holder would not take less than its subjective view of the value of its claim. Second, while it might accept a compromise of damages that is equal to the value of its claim, why would it? The entire point of the example in Schildkraut discussed by the Court is that there is a compelling incentive to compromise damages in a way that achieves for the patent holder more than its subjective value of its claim. That is, by compromising damages, the patent holder retains more monopoly than it expects to get through continued litigation.[186]

The *Actavis* approval of settlements that compromise damages has substantial (albeit not unexpected) implications. Extrapolating from Hypothetical 2, because the compromise of damages appear to be per se lawful, we can expect the settlement will be anticompetitive in most patent litigations where the patent holder has substantial market power. The majority could have applied merits analysis to these cases, which would occasion litigating the patent case inside the antitrust case.[187] That would have been too much for a Court that was unanimous in its attempt to minimize the litigation of patent disputes inside antitrust cases. But given the implications of providing litigants such carte blanche in traditional patent cases, the result of *Actavis* is to ameliorate the smaller problem, Hatch-Waxman settlements, while seemingly providing the seal of approval for a more widespread anticompetitive effect, traditional patent settlements that compromise damages. So using the phrase of Edlin et al, there is already a "gaping loophole." In fact, there is more than a gaping loophole given that traditional patent settlements are likely the bigger competitive problem. The words of *Actavis* seem inconsistent with the economic logic that resulted in the condemnation of net reverse payments.

According to the dissent, the majority's focus on money is "a distinction without a difference."[188] The dissent is surely correct about there being no difference. And, that is why some lower courts did not adopt the distinction offered by the *Actavis* majority. These courts, as Carrier would say, went with "economic effect rather than … formalistic line drawing."[189] The *Actavis* majority, however, did not eschew such formalistic line drawing. The lower courts, on the other hand, looked for a limiting principle, but could only find a limitation and many went with principle. But they did not grapple with the broader implications of their condemnation of non-cash reverse payments.

There is another distinction worth considering. In the case of the compromise of damages, there is no red flag that is the equivalent of cash because it is difficult to determine whether the payment from the alleged infringer to the patent holder reflects an anticompetitive intent. There is no easy way to distinguish between the patent holder obtaining the full measure of expected damages and the patent holder accepting compromised damages to retain its monopoly. So the

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[186] The *Actavis* Court offers a "cf." citation to *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004), for the proposition that "collusion" is "the supreme evil of antitrust." *Id*. However, both a settlement where the litigants compromised damages and a settlement containing a net reverse payment amount to the same sort of collusion and do not seem to be things that are "quite different."

[187] Or it might have reduced the number of settlements because, as we have shown, the potential antitrust damage from settling could generate a negative expected value.

[188] *Actavis*, 133 S. Ct. at 2243 (Roberts, C.J., dissenting).

[189] Carrier, *supra* note **Error! Unknown switch argument.**8, at 715 (quoting *Sylvania*, 433 U.S. at 58-59).

Court selected a rule of decision, per se legality, that is even more lenient than the potential scope of the patent test that it so roundly condemned in the Hatch-Waxman context.

Looking at this issue from another perspective, consider a generic that could enter at risk, after the 30-month Hatch-Waxman stay expired, as permitted by statute if the FDA has approved the relevant ANDA.[190] Launching at risk means the generic is facing the risk of losing the infringement case.[191] Suppose, hypothetically, the brand believes it has an 80 percent chance of prevailing in Hatch-Waxman litigation. There are ten years left on the patent life and it will make $1 billion every year that it has no competition and $100 million every year there is competition. The brand's expected value of litigation is $8.2 billion. The generic believes it has a five percent chance of prevailing and it would make $100 million every year it is on the market. Its expected value of the litigation is $50 million.

The brand and generic hatch the following scheme. The generic will enter in year 1 "at risk" and will make $100 million that first year. After the year, the brand and the generic will settle the litigation with the generic leaving the market for the remaining nine years. The generic has doubled its expected value of litigation. The brand will make $100 million in the first year and $9 billion over the next nine years. This compromise of damages has no explicit net reverse payment and would seem to have the *Actavis* stamp of approval. The settlement exceeds the brand's expected value of litigation by $900 million. From the brand's perspective, consumers are worse off.[192] So it is hard to fathom the economic rationale of the *Actavis* Court when it approved traditional settlements of a patent lawsuit where "a party . . . receives a sum equal to or less than the value of its claim."[193]

Earlier, this article posed the question of whether we could distinguish *Actavis* from other settlements and other conduct because it was so different from anything else. That is, Congress created the potential for anticompetitive settlements and some unique solution had to be found to prevent such settlements.[194] If this distinction had merit, courts might limit the *Actavis* methodology to Hatch Waxman settlements. But our analysis here suggests that there is little economic difference between reverse payments in the Hatch Waxman context and other forms of settlements.

The district court in *Nexium* offers a surprising perspective on the antitrust vulnerability of conventional settlements. It ignored the Supreme Court's approval of compromised damages. Plaintiffs claimed that a settlement in a separate litigation by some of the defendants was so low that it "constituted a significant forgiveness of debt" by one defendant to delay the launch of a generic. The lower court denied defendants' motions for summary judgment based on this

[190] 21 U.S.C. § 355(j)(5)(B)(iii).

[191] *Nexium*, 842 F.3d. at 41.

[192] From the generic's perspective, consumers are better off. The generic's expectation that it had only a five percent chance of prevailing means that the generic's expects that consumers will pay $9.5 billion if the matter is litigated to a conclusion. The settlement generates costs to consumers of $9.2 billion.

[193] *Actavis*, 133 S. Ct. at 2233. In the example the Court cites, the sum received is less than the value of the claim and that is why the anticompetitive effect is economically identical to a cash reverse payment.

[194] See page 26, *supra*.

settlement, agreeing with plaintiffs that there was sufficient evidence to proceed to trial on the theory.[195] The Supreme Court approval of compromised damages appears not to have impressed the *Nexium* district court. If that is a court's response when there is no red flag, imagine how the post-*Actavis* courts will handle the situation where there is a red flag. That is the topic of the next section.

Applying *Actavis* to Difficult IP/Antitrust Cases

Our investigation of the *Actavis* decision has led to the conclusion that a net reverse payment could harm consumers. In fact, in the absence of a rule regulating net reverse payments in some fashion, we can expect that most settlements containing such payments would be anticompetitive. We have also concluded that evaluating the potential scope of the patent is not sufficient to prevent such anticompetitive effects. The *Actavis* Court's endorsement of compromised damages has even less to offer consumers than potential scope-of-the-patent analysis. That leaves us with *Actavis* analysis and merits analysis as possible methodologies to prevent anticompetitive effects.

There are important distinctions between the two forms of analysis. We have noted many weaknesses in *Actavis* analysis. For example, *Actavis* analysis relies on the intent of a single party to inform courts whether an agreement is anticompetitive. *Actavis* analysis abandons the preponderance of the evidence standard.[196] Such weaknesses may affect the lower courts' propensity to extend *Actavis*.

We have also observed that there is a red flag in net reverse payments that may indicate, but not always indicate, an anticompetitive intent by one of the parties settling the Hatch Waxman litigation. If there is no red flag, merits analysis may be the only option to protect consumers from certain anticompetitive agreements. It seemed important to the *Actavis* Court that the net reverse payment involved money as it used money to distinguish such a payment from a compromise of damages.[197] But the trend in the lower courts has been to treat other forms of net reverse payments just like money.

Let us now return to the market division agreement where Hovenkamp et al. hypothesize that a patent holder and an alleged infringer divide the market along the Mississippi to settle the infringement suit.[198] According to Hovenkamp et al., if the patent were valid and infringed, this "would be a completely legal license of a patent, because the Patent Act expressly provides that the patentee may make territorially restricted licenses."[199] The question for the treatise authors is

[195] *Nexium, 842 F.3d* at 45.

[196] A reverse payment settlement that excludes the generic for the entire life of the patent would be anticompetitive even if everyone agrees that the brand was 90 percent likely to prevail in the Hatch-Waxman litigation. In other words, the payment is deemed anticompetitive even though it is more likely than not that the patent would exclude the generic for the life of the patent. And, if the parties had not settled and the brand prevailed in the litigation, as was 90 percent probable, the generic would have been excluded for the life of the patent.

[197] We found that it is not the case that a net reverse payment is distinguishable from the compromise of damages because the compromise of damages is less than the value of the claim.

[198] *Hovenkamp et al.*, *supra* note **Error! Unknown switch argument.**, § 7.3[A], at 7-17.

[199] *Id*.

whether the settlement "was a reasonable accommodation given both the presence of IP rights and the scope of their claims."[200] This is presumably resolved through merits analysis, by litigating the patent claim in the antitrust case. If it is more likely than not that the patent holder would prevail in litigation, the market division is legal.

That is not the outcome under *Actavis* and the Court of Appeals no-AG cases. Under these precedents, it does not matter whether the patent is valid and infringed as the patent law must yield to antitrust considerations. Because of these considerations, this market division would be unlawful in almost all cases. First, there is non-cash net reverse payment that is similar to the exclusive generic license in the no-AG cases. The market division is also a red flag indicating an anticompetitive intent: an intent to prevent the chance that litigation would invalidate the patent or establish that the alleged infringer was not actually infringing. To illustrate, suppose the two parties expect that the odds that the patent holder would vindicate its patent through litigation is 60 percent. The patent holder may nevertheless agree to a market division that retains more than 60 percent of the monopoly. The alleged infringer is happy to accept the market division because its small monopoly yields more in profits than competition. As a result of the market-division settlement, the consumers lose the 40 percent chance (assuming the litigants' expectations are correct) that the patent will be held invalid or not infringed.[201]

Thus, there does not seem to be any property of the settlement that would distinguish it from *Actavis,*[202] suggesting that the courts can condemn such a settlement without engaging in merits analysis. If, merits analysis had been employed however, the courts would have blessed the market division settlement six out of ten times.[203]

Ironically, the threat of either *Actavis* or merits analysis would incentivize the litigants to settle by compromising damages. If they are able to do so,[204] consumers will still face a monopoly, the only difference being that they will face one monopolist rather than two monopolists situated on either side of the Mississippi. To be sure, there may be cases where there are not enough in potential damages for a compromise of damages to do the trick. But where it does, the Supreme Court has provided a guide as to how to circumvent *Actavis* and achieve the anticompetitive effect that *Actavis* sought to prevent.

If *Actavis* were to be extended into this realm, a market division is only one of many red-flag ways that the patent holder can preserve the monopoly that an alleged infringer is challenging. It

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[200] *Id*. § 7.3[A], at 7-18.

[201] Even if the litigants believe that the patent holder is 90 percent likely to prevail, the litigating parties could develop a market division that yields a better outcome for the litigants than it does for the consumer.

[202] While no money changes hands in this hypothetical, it is not the equivalent of the patent splitting settlements without net reverse consideration that *Actavis* endorses. The endorsed settlements result in competition when the generic enters the market. The settlement in this hypothetical gives the generic a valuable monopoly in order to avoid any competition.

[203] Perhaps the antitrust risk to the litigants is too high to accommodate the settlement.

[204] The litigating parties will not always be able to settle this way. It depends on the parties' expectations and how much damage has accrued that could be compromised. If the issue is that there are not yet enough damages to compromise, the parties could attempt to delay the litigation so that damages accumulate.

could acquire the alleged infringer;[205] it could agree to licensing fees that are high enough to preserve the monopoly price;[206] it could set the price of the product of the alleged infringer that is exploiting the patented technology.[207]

Settlements involving blocking patents are more complex. To analyze blocking patents, assume that the litigants are competing and again the settlement contains a market division agreement. Under one view, *Actavis* would condemn this settlement: there is a red flag, a bribe removing the chance that litigation will find that neither set of patents block competition. Under this view of *Actavis*, consumers should not be denied that chance of competition. And, there is probably little downside for consumers: if the court finds that the patents are blocking, the parties likely will reach an accommodation so that they do not have to exit the market. That accommodation may be the market division agreement that was previously disfavored under *Actavis*. But after litigation, we have a definite outcome that would otherwise keep all the participants out of the market. *Actavis* logic is unlikely to question rectifying such an outcome.

There is another perspective, however. Suppose that both parties to the litigation believe there is a 100 percent chance that the patents are blocking and neither party can operate without a license. This suggests that a market division is not always a red flag when patents are allegedly blocking. The rival patent holders are agreeing to the market division because they are certain that the patents are blocking. While they could go through the litigation motions, they can save the cost of litigation by entering into the market division now. If the parties are right, the agreement is procompetitive.

There is a third perspective on the blocking patent situation. Consider the case where the litigants challenging the validity of each other's patents are already competing. After discovery, they come to believe that each is infringing valid patents. *Actavis* logic suggests that they must litigate because of the chance that consumers would get more competition if the patents are judged invalid. But are the courts going to prohibit a compromise that allows the litigants to keep competing? If they do, the litigating parties may have no choice but to withdraw from the market as now each believes they are infringing a valid patent. Not only do consumers lose the competition, the products are lost from the market entirely. This may not be in the consumer's interest, depending on how long consumers will have to do without, compared to the probability and benefits of competition after the resolution of the litigation.

So there are multiple characteristics of *Actavis* that we need to reckon with when patents are allegedly blocking. The market division is a red flag except under the extreme circumstance

[205] *See IBM Corp. v. Platform Sols., Inc.*, 658 F. Supp. 2d 603 (S.D.N.Y. 2009), for a case where an IP holding plaintiff acquired a competitor in order to shut it down.

[206] *See Bement v. Nat'l Harrow Co.*, 186 U.S. 70, 93 (1902) where the Court approved a settlement that permitted the alleged infringer to produce the patent holder's agricultural harrows at a specified royalty rate. Under the settlement, the harrow had to be sold at a price dictated by the patent holder and the alleged infringer agreed to only use the patent holder's technology.

[207] *Gen. Elec.*, 272 U.S. at 488 (a patent license to a competitor could dictate the price the competitor could charge for goods that embody the patent). *See also United States v. Huck Mfr. Co.,* 227 F. Supp. 791 (E.D. Mich. 1964), aff'd by and equally divided Court, 382 U.S. 197 (1965) where, to settle a patent dispute, the patent holder agreed to license its patent to Huck and not to license anyone else. In addition, the license set the price at which Huck could sell the patented product.

where the litigants are 100 percent certain that they are each infringing a valid patent. Consumers can be harmed because they are losing the opportunity for litigation that might invalidate all the patents and result in competition. On the other hand, there are circumstances where consumers would be harmed because they lose the benefits of the technology entirely for some time.

If application of *Actavis* seems too harsh when blocking patents are involved, does merits analysis fare better? Assume the parties settle and divide the market and consumers then file an antitrust suit. In the extreme case referenced above, the defendants need not worry because they are 100 percent certain of prevailing. In other cases, they are not so certain. Suppose they are 80 percent certain. They now must balance the antitrust risk of treble damages against the benefits of exploiting their patents through the market division. The patent litigants may or may not take the risk, and that may or may not include the risk of continuing to compete for the duration of the patent litigation. Consumers may object to merits litigation, arguing they are always entitled to the chance of competition that the market-division settlement snuffed out. But consumers are no worse off if damages achieved through merits litigation reflect patent litigation expectations, as consumers would prevail in the antitrust case often enough to yield the average consumer's expectations (even before damages are trebled).

The agreements discussed herein do not have to be the result of litigation. Parties may reach accommodations before litigation. It is also possible that the blocking issue can involve many parties, not just two. And, it is possible that the parties will not be willing to enter the market if they think that other parties have valid patents that may block their entry. Simple cross licensing without licensing fees may not solve the problem because that will prevent patent holders from capturing the monopoly profits that the patent law permits. Under such circumstances, some form of agreement that permits the parties to share the monopoly profits may be necessary to get the relevant products on the market. Such an agreement might involve some cross payments if certain patents are deemed stronger than others. All of these arrangements involve some form of payment that is suspicious under *Actavis*. But in the absence of such arrangements, no one may be able to compete and customers may suffer. Putting the patent holders through multiple litigations might or might not mean that consumers will have to wait years before the products are available.

In these blocking situations, *Actavis* may not seem like a very satisfying solution, particularly to patent holders, because anything more than a simple royalty-free cross license could be viewed as a bribe protecting monopoly profits. Under merits analysis, the risk the settling parties will lose the patent litigation means that the parties may prefer to litigate the patent merits and this may take years. While the potential scope of the patent methodology permits settlement, it does so at a substantial cost to consumers. Of course, patent holders may find solutions to these problems without resorting to the rule of the *Actavis* dissent. So for example the microprocessor industry has engaged in extensive cross licensing without which no one would be able to produce a microprocessor. To be sure, the patent holders may not have the maximum benefits of their individual patent monopolies but they are able to market microprocessors.[208]

[208] *See Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346 (Fed. Cir. 1999), for an example of an attempt to withhold intellectual property on the part of one firm where another firm refused to trade intellectual property.

Certain licenses may involve no patent litigation or immediate prospects of patent litigation. Consider a hypothetical inspired by the *Actavis* dissent.[209] Under *United States v. General Elec. Co*.,[210] a patent holder may license its patent subject to a fixed resale price.[211] Under our *General Electric* hypothetical, a patent holder/manufacturer is competing with another manufacturer that is possibly infringing the pertinent patent. The rivalry has driven the price of the goods in question to competitive levels. The patent holder then licenses its patent to the competing manufacturer. Under the license, the patent holder dictates the wholesale price of the competing manufacturer's product and takes a healthy licensing fee. The patent holder unilaterally raises its wholesale price to the price it set in the patent license. The licensee unilaterally abandons its production of the non-patented good as it can make much greater margins on the sale of the patented goods at the fixed price. Consumers, who are all of a sudden paying much more for the relevant product, initiate an antitrust action, contending that the agreement violates the Sherman Act and that the patent license is an invalid cover for an anticompetitive agreement. The patent holder waives privilege and offers internal attorney analysis that concludes that there is an 80 percent likelihood that the patent would withstand a legal challenge. Its licensee also waives privilege; its internal analysis shows that it decided not to challenge the patent because it concluded there was an 80 percent probability that it would lose the patent litigation. The plaintiffs then abandon any attempt to challenge the patent on the merits in the antitrust litigation, arguing instead that the 20 percent chance that the patent would be found invalid is sufficient to find a violation under *Actavis*. The plaintiffs argue that a Hatch-Waxman settlement with these same terms would be condemned and that the harm to consumers in the challenged license is economically identical to a Hatch-Waxman settlement on similar terms. The patent holder and its licensee argue that they should receive summary judgment because the only evidence in the record is that it is more likely than not that the patent is valid. Under *Actavis,* the plaintiffs would seem to have a point. Under a merits analysis, having abandoned any attempt to establish the merits, the plaintiffs should be thrown out of court.

Heretofore, we have shown the similarity *on average* in outcome under merits analysis and *Actavis* analysis so long as the brand's expectations about the litigation outcome is correct and we are dealing with a large enough number of litigations so that *on average* is meaningful. But this hypothetical is different. Extending *Actavis* logic to this license, the court would condemn the hypothetical agreement because consumers are missing out on the chance that alleged infringer was not infringing or that the patent at issue was not valid. If courts follow this logic, they would condemn almost all such agreements where expectations are revealed. Under merits analysis, which ignores the parties' expectations, the courts would uphold the agreement a good portion of the time.

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[209] *Actavis*, 133 S. Ct. at 2245 (Roberts, C.J., dissenting) ("For example, when a patent holder licenses its product to a licensee at a fixed monopoly price, surely it takes away some chance that its patent will be challenged by that licensee. According to the majority's reasoning, that's an antitrust problem that must be analyzed under the rule of reason. *But see General Elec. Co.*, 272 U.S. at 488, 47 S.Ct. 192 (holding that a patent holder may license its invention at a fixed price).)."

[210] *Gen. Elec.*, 272 U.S. at 488-490.

[211] *See also Actavis*, 133 S. Ct. at 2239 (Roberts, C.J., dissenting) ("although it is *per se* unlawful to fix prices under antitrust law, we have long recognized that a patent holder is entitled to license a competitor to sell its product on the condition that the competitor charge a certain, fixed price").

Taking this one step further, even if there were no waiver of privilege, courts could reason that consumers were losing an opportunity that patent litigation would have resulted in more competition leading to condemnation of the agreement. Like *Actavis,* the parties are sharing a monopoly rather than litigating. The only way out of this trap for the parties would be to continue to compete or for the patent holder to file suit claiming infringement. This may put the competitor in an intolerable position as it comes to realize that its competition is exposing it to growing potential damages. Such considerations are likely to weigh on the courts and generate doubts about applying *Actavis* to this type of situation.

Antitrust Guidelines for the Licensing of Intellectual Property

On January 13, 2017, the U.S. Department of Justice and the Federal Trade Commission issued revised Antitrust Guidelines for the Licensing of Intellectual Property.[212] Given the ambiguities of *Actavis*, one would think that the moment had arrived for guidance on *Actavis*'s application. However, the Guidelines offer no such guidance. There is one germane passage, in which the federal antitrust agencies state: "antitrust concerns may arise when a licensing arrangement harms competition among entities that would have been actual or potential competitors … in the absence of the license (entities in a "horizontal relationship")."[213] In an accompanying footnote, the Guidelines state: "[a] firm will be treated as a potential competitor if the Agency finds that it is *reasonably probable* that the firm would have become a competitor in the absence of the licensing arrangement."[214]

Applying this to a Hatch Waxman settlement where there was a net reverse payment to keep the generic out of the market for some period, such payment does not tell us whether the generic's entry was reasonably probable. As our hypotheticals demonstrate, a brand has an incentive to make a net reverse payment even if it believes it is 90 percent likely to prevail in the Hatch Waxman litigation. *Actavis* would condemn such settlements. But that is not the case under the Guideline's *reasonably probable* standard because it is not likely that the generic would enter (assuming the brand's expectation is correct). It would seem that the only way to determine the reasonable probability of entry is by assessing the merits of the patent.

The Guidelines footnote at issue continues: "[i]n some contexts, however, the elimination of a would-be competitor is subject to condemnation by antitrust law even though the firm's prospects may be uncertain. *See, e.g.,* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2236 (2013)."[215] For the antitrust agencies, it appears that Hatch-Waxman settlements are an exception to the general reasonable-probability standard. However, the plural "contexts" does offer a hint of more. Unfortunately, the Guidelines tell us nothing about the contexts where we can expect more.

[212] *Revised IP Guidelines*, *supra* note 6.

[213] *Id.* at 7-8.

[214] *Id*. n.27 (emphasis added).

[215] *Id*.

Actavis beyond the IP/Antitrust Interface

Consider the case where both the brand and the generic agree that the brand has a 90 percent chance of prevailing in the Hatch-Waxman litigation. The entire market value of the generic is based on its ten percent chance of prevailing in the litigation. In this hypothetical, the brand settles the Hatch-Waxman litigation by acquiring the generic, keeping the generic out of the market in perpetuity. And, being honest folks, the brand acknowledges that it acquired the generic to maintain its monopoly for the entire patent life and the acquisition was the most convenient way to bribe the generic to maintain the monopoly. Applying the *Actavis* methodology, this acquisition appears to be unlawful because a net reverse payment is questionable even if it eliminates only "a small risk of invalidity."[216]

The acquisition in this hypothetical is not unlawful in nine out of ten litigations under merits analysis assuming the litigants are correct in their expectation regarding patent litigation. Nor is the acquisition unlawful under Section 7 of the Clayton Act. Under that statute, the theory of harm would be the loss of actual potential competition.[217] Because it is *likely* that the generic would not be able to enter, the acquisition would pass muster. Using *Actavis* methodology makes quite a difference in this case.[218]

If the courts are going to extend *Actavis* to this sort of acquisition, why confine the analysis to acquisitions that implicate the IP/antitrust interface? Consider an acquisition where a monopolist, without IP, acquires a potential entrant that might challenge its monopoly. The evidence establishes that there is only a 10 percent chance that the potential entrant would actually enter. There are no efficiencies to the acquisition. In fact, the monopolist being quite honest explains that it was worth the price of the acquisition to avoid the 10 percent chance that the acquired firm would enter the market and undermine its monopoly power.

Of course, in the real world, our monopolist will not be so honest about its intentions. But there may be internal non-privileged documentation that allows the same conclusion to be rendered: there is a 10 percent chance that the acquisition will diminish future competition and there are no countervailing efficiencies. Under established actual potential competition analysis, the acquisition would be lawful because it is *un*likely that the acquisition will diminish future

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[216] *Actavis*, 133 S. Ct. at 2236.

[217] The Supreme Court has never adopted the actual potential competition doctrine, leaving it open for another day on two occasions. *United States v. Falstaff Brewing Corp.*, 410 U.S. 526, 537-38 (1973); *United States v. Marine Bancorp.*, 418 U.S. 602, 639 (1974). Courts of Appeal have used different standards for judging the actual potential competition. For example, in the Second Circuit the plaintiff must show that entry is "likely." *Tenneco Inc. v. FTC*, 689 F.2d 346, 352 (2d Cir. 1982). The Fourth Circuit requires "clear proof" of entry. *FTC v. Atl. Richfield Co*., 549 F.2d 289, 294-95, 300 (4th Cir. 1977). In the Merger Guidelines the issue is "whether the merging firms have been, or *likely will become* absent the merger, substantial head-to-head competitors." Horizontal Merger Guidelines, *supra* note 81, § 2.1.4 (emphasis added).

[218] Susan A. Creighton and Scott A. Sher propose applying the *Actavis* methodology to such acquisitions. *Resolving Patent Disputes through Merger: A Comparison of Three Potential Approaches*, 75 Antitrust L.J. 657 (2009); *see also* Jonathan M. Orszag and Loren K. Smith's proposed probabilistic treatment of a merger efficiency defense to an otherwise anticompetitive merger. *Toward a More Complete Treatment of Efficiencies in Merger Analysis: Lessons from Recent Challenges*, The Antitrust Source 6-7 (October 2016).

competition.[219] Using *Actavis* methodology, there is a risk to the monopoly that is eliminated by the acquisition. The risk is equivalent to the risk in a Hatch Waxman settlement where the brand that thinks it is 90 percent likely to prevail in patent litigation makes a reverse payment to retain 100 percent of the patent life. So if the courts are guided only by the "economic effects" condemned in *Actavis* they will find the acquisition unlawful.

Notice the use of the term "economic effects" in the last paragraph. Earlier, this article posed the question of whether *Actavis* was creating a new evidentiary standard or whether it was simply offering a policy prescription. It also asked whether it matters.[220] Our hypotheticals suggested that the characterization does not matter. If our monopolist acquires a firm that only has a ten percent chance of entering the relevant market, the courts, deploying *Actavis,* could condemn the acquisition because the courts no longer adhere to the more-likely-than-not evidentiary standard. Or, it could condemn the acquisition because as a matter of policy, we should not tolerate an acquisition that has any chance of generating an adverse effect (not counterbalanced by procompetitive effects). Or, it could condemn the acquisition because it has redefined the meaning of "anticompetitive:" any increased chance of a net adverse effect is "anticompetitive." No matter how we characterize the *Actavis* test, the acquisition cannot stand even though it is more likely than not that the acquisition would not adversely affect consumer welfare compared to the but-for world.

If this seems fanciful, consider a February 28, 2017 Federal Trade Commission staff blog post about an FTC challenge and settlement concerning an acquisition by Questcor Pharmaceuticals, Inc. (now a subsidiary of Mallinckrodt plc and renamed Mallinckrodt ARD Inc.).[221] According to the Commission's complaint, Questcor had a monopoly in the United States on adrenocorticotropic hormone (ACTH) therapies with its drug Acthar.[222] Acthar is used to treat, among other afflictions, Infantile Spasms, a serious seizure disorder suffered by some newborns. Questcor had acquired Acthar in 2001 and had thereafter increased the price of the drug from $40 to over $34,000 per vial.

To maintain its monopoly, Questcor outbid several other suitors to acquire another drug, Synacthen Depot, used for ACTH therapies in several countries, not including the United States. Because Synacthen was not approved for use in the United States, it would have faced a long and difficult road to achieve approval.

The FTC complaint alleged that the acquisition violated Section 2 of the Sherman Act, which outlaws unlawful monopolization. The complaint did not allege that an acquirer other than Questcor was likely to obtain U.S. regulatory approval. According to the blog post:

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[219] Courts are split on the quantum of proof necessary to establish the probability of entry in an actual potential competition case, but no court has required the plaintiff to prove less than a likelihood of entry. *See, e.g., FTC v. Atl. Richfield Co.*, 549 F. 2d289, 294-95 (4th Cir. 1977) (requiring "clear proof"); *Tenneco, Inc. v. FTC*, 689 F.2d346, 352 (2d Cir. 1982 (requiring that entry is "likely").

[220] See page 27, *supra.*

[221] David Gonen, Federal Trade Commission, *Protecting challenges to monopolies*, Feb. 28, 2017, https://www.ftc.gov/news-events/blogs/competition-matters/2017/02/protecting-challenges-monopolies.

[222] FTC v. Mallinckrodt ARD Inc., No. 1:17-cv-00120 (D.D.C. Jan. 25, 2017) (complaint) *available at* https://www.ftc.gov/system/files/documents/cases/170118mallinckrodt_complaint_public.pdf.

> The Commission's approach is consistent with the D.C. Circuit's en banc decision in *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001), in which the court concluded that Microsoft's elimination of "nascent" threats violated Section 2. In their treatise, Areeda and Hovenkamp similarly advocate preventing a monopolist from acquiring any firm that is a "more-than-fanciful possible entrant." Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 701d.[223]

In other words, the FTC was *not* alleging that it was *likely* that Questcor's acquisition resulted in less competition than in the but-for world where another firm acquired Synacthen. It does not appear that there is an issue here with red flags. The *Actavis* Court looked for red flags to avoid second guessing every litigation settlement. Where a patent litigation is settled with damages, we cannot be certain whether there was a compromise of damages that manifested an anticompetitive intent. If every damage settlement is second guessed, there would put quite a damper on such settlements. On the other hand, challenging our hypothetical acquisition or the Questcor acquisition would not discourage settlements. In fact, the evaluation is rather conventional except for the standard of proof. So there does not seem to be any obstacle to applying *Actavis* to such acquisition if the courts are untroubled by the revolutionary impact on antitrust analysis generally.

Applying the *Actavis* evidentiary standard rather than the preponderance of the evidence standard can make a difference in the outcome of potential competition cases. In the potential competition hypothetical, we are not asking about the expectation of prevailing in litigation that did not occur because of a settlement. Instead, we are asking about the chance of an anticompetitive effect irrespective of any particular expectation. Assume for example that there are ten potential competition challenges over ten years. One such acquisition has a ten percent chance of an anticompetitive effect and there are no efficiencies, which we will call the "net anticompetitive effect." The second has a twenty percent chance of a net anticompetitive effect. And so on, until we get to the tenth acquisition with a 100 percent probability of a net anticompetitive effect. Under conventional evidentiary standards, the courts would enjoin only five of the acquisitions—those where the chance of a net anticompetitive effect ranges from 60 percent to 100 percent. Extending *Actavis*, the courts would enjoin all these potential competition acquisitions. The rationale for doing this, like the *Actavis* situation, is that the courts should stop any conduct that creates a chance of an anticompetitive effect where there are no countervailing efficiencies.[224]

In such cases, the courts would not be relying on the intent of a single party. Instead the courts would be relying on the same sort of substantive analysis that courts always use; the only difference being the change in the standard of proof. Nor does the result suffer from the downsides of the *General Electric* hypothetical. In that hypothetical, if *Actavis* were the rule, the alleged infringer might stop competing. There is no such downside here.

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[223] Gonen, *supra* note 214.

[224] If there are potential efficiencies, the chance of a net anticompetitive effect should not be sufficient to condemn the acquisition. Instead, the acquisition should only be condemnation if the chance of a net anticompetitive effect outweighs the chance of and benefits of the efficiencies that cannot be realized.

But why stop with actual potential competition cases? Assume a merger between two horizontal competitors that has a 10 percent chance of lessening net competition. Consumers are harmed because they miss out on the 10 percent chance that they would reap the benefits of competition if the merger were blocked. So instead of the court instructing the jury on the preponderance of the evidence standard, the court would instruct the jury that it should find the acquisition unlawful if there were no efficiencies and *any chance* that the acquisition would result in a lessening of competition.

We could apply the *Actavis* logic across the board in antitrust matters and perhaps elsewhere. Take for example, an agreement between competitors that has no cognizable efficiencies and internal documents reveal that the parties' intent was to avoid a ten percent chance that competition would reduce prices. The courts could condemn this agreement under the logic of *Actavis*. The court's condemnation does not require actual adverse effects or any showing of market power beyond the documents revealing the parties' intent. Would courts actually launch themselves onto such a slippery slope?

Where Are We Going?

Actavis is a challenge to the entire body of antitrust law. As we have seen in the no-AG court of appeals decisions, the courts are willing to extend *Actavis* where they cannot find a reasonable principle limiting its application. These courts focused on the economic logic of *Actavis*, not *Actavis*'s words and examples. Following the economic logic can take us far afield, upending many of the concepts that seem fundamental to antitrust analysis and burdens of proof in civil litigation.

As far as patent litigants are concerned, *Actavis* presents some danger to any sort of settlement of litigation that contains consideration. As *Nexium* shows, despite the Supreme Court's clear statement, even the compromise of damages is vulnerable. The logic that motivated *Actavis* would undermine many aspects of conventional antitrust analysis. In the context of the patent interface, the likelihood that a patent is valid and infringed would not necessarily protect the patent holder from antitrust liability. The patent's right to exclude may give way to antitrust considerations and indeed might be replaced by probabilistic analysis under which even a 90 percent likelihood that the patent was valid and infringed would not vindicate a patent-based exclusion. Nor can patent holders rely on the conventional rule of reason analysis to show that they have no market power. This too is up in the air as courts may interpret any payment greater than litigation costs as a demonstration of market power. Under *Actavis* logic, the payment also reveals intent to harm that might take precedence over any more traditional showing of adverse effects.

The core of its economic logic is that consumers are denied an opportunity for more competition even if it is unlikely than such competition would ever occur. Even though it is at odds with the preponderance of the evidence standard in civil litigation, the courts could prohibit a monopolist's acquisition of a potential entrant if there are no efficiencies and only a ten percent chance that the potential entrant would actually enter.

There are considerations that may slow down or stop the general application of *Actavis*. *Actavis* contains its own contradiction, condemning cash payments but not the compromise of damages

that likely does more damage to the economy. It permits anticompetitive settlements where there are no reverse payments. It may prohibit procompetitive settlements by failing to account for risk aversion. It focuses on intent evidence to the exclusion of much more persuasive inquiries regarding anticompetitive effects. It is the anticompetitive intent of a single party that matters even in the absence of evidence regarding the intent of the other settling party. It generates a virtually unworkable means of calculating damages. It may be in error in its belief that firms can predict litigation outcomes. It forces the courts to rely on litigant's subjective expectations about litigation outcomes rather than the merits of the claim. It is inconsistent in that it is guided by certain predictions regarding outcomes while ignoring other predictions entirely. It seems virtually unworkable as a standard when the anticompetitive effect must be balanced against efficiencies. And, it is dismissive of evidentiary standards central to civil litigation. If the courts cannot stomach these outcomes, they may wish to reconsider remaining faithful to the economic logic of *Actavis* whenever an extension of *Actavis* is under consideration.

One might have hoped that the antitrust agencies would have thought this all through before seeking an *Actavis*-type solution to the Hatch-Waxman problem. And, one might have hoped that they would have reflected their thinking in the modified Intellectual Property Guidelines. But the antitrust agencies appear to be missing in action.