INTRODUCTION

In their article “Activating Actavis,”¹ Aaron Edlin, Scott Hemphill, Herbert Hovencamp, and Carl Shapiro describe their interpretation of the U.S. Supreme Court’s Actavis decision and how a rule of reason approach should be applied in antitrust litigation involving reverse payment settlements of pharmaceutical patent litigation. The Edlin et al. approach has several major flaws, and a complete response to those flaws is beyond the scope of this article. This article instead focuses on two specific flaws of the Edlin et al. proposed approach: (1) the authors’ failure to consider several justifications for payments from brand companies to generic companies that are not indicative of a brand company paying a generic company to delay generic entry beyond the date consistent with the expected outcome were the case to be litigated, and (2) the authors’ flawed definition of the “but-for” world.

BACKGROUND

In 1984, the Drug Price Competition and Patent Term Restoration Act, also referred to as the Hatch-Waxman Act, was passed.² The Act made a number of changes to the pharmaceutical drug approval process and created incentives for generic companies to challenge the patents of branded drugs. Some of the settlements of the litigation resulting from these patent challenges have involved so-called “reverse payments” by the brand company to the generic challenger. Many reverse payment settlements have been alleged to cause antitrust harm by the Federal Trade Commission (FTC) and private plaintiffs. Federal circuit courts disagreed about how to evaluate these cases and as a result of this disagreement the Supreme Court agreed to hear one of these cases, FTC v Actavis, in 2013. While the Supreme Court adopted a rule of reason approach, it provided little guidance for lower courts about how to implement this approach.

A. Hatch-Waxman Act

As the name suggests, the Drug Price Competition and Patent Term Restoration Act both extended the patent life of the patents that protect newly approved innovative drugs and created measures to increase generic competition in pharmaceutical drug markets. The life of patents that protect drugs was extended by up to five years to help make up for the time it takes to conduct clinical trials and receive approval from the Food and Drug Administration (FDA).³ The Act sought to increase generic competition in pharmaceutical markets by creating a shortened approval process for generic drugs thereby decreasing the costs associated with the approval of these drugs. In particular, following the passage of the Act, generic companies could file an abbreviated new drug application (ANDA) that demonstrated that their generic drug was bioequivalent to the innovative drug and could rely on the clinical trials conducted for the innovative drug that showed the drug was safe and effective (rather than having to conduct such trials themselves).

The Act also set up a process for generic companies to challenge the patents covering branded products without having to enter the market and provided incentives for generic companies to challenge these patents. When filing an ANDA with the FDA, generic companies must make one of four certifications:

• Paragraph I Certification: No patents cover the brand;
• Paragraph II Certification: Only expired patents cover the brand;
• Paragraph III Certification: The generic will not enter until the patents covering the brand expire;
• Paragraph IV Certification: The patents covering the brand are invalid and/or will not be infringed by the generic.

The filing of an ANDA with a Paragraph IV Certification is considered an act of infringement. Following the filing of a Paragraph IV challenge, the Act stipulates that the

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brand company has 45 days to file suit against the generic company for patent infringement and if it does it is granted an automatic 30-month stay of FDA approval. One of the unique features of this situation is that generic companies can challenge the patents covering branded products without actually entering the market. Therefore, unlike in other patent infringement cases, generic companies do not face the risk of having to pay substantial damages to the patent holder as a result of infringing their patent. Instead, generic companies only face litigation costs even if the court finds the patent valid and infringed. This provides the generic challengers with substantial leverage over the innovative drug companies, which have far more at risk in such patent litigation.

The Act further incentivizes generic challenges to brand company patents by awarding the first generic company (or companies) to file an ANDA with a Paragraph IV Certification 180 days of exclusivity upon the successful resolution or settlement of patent litigation stemming from such a case. That is, the generic company receives 180 days during which no other generic company will be granted FDA approval to market a generic version of the drug in the market. The 180 days of exclusivity is very profitable for generic companies; in fact, most generic profits are earned during this period. The potential profits that can be earned during the exclusivity period, along with the low costs of filing ANDAs and challenging patents, has led most branded drugs (and virtually all with substantial sales) to experience patent challenges.

B. Reverse Payment Settlements

Patent litigation is risky for both parties, but particularly for pharmaceutical patent holders. Often such companies face the loss of substantial revenues streams. For smaller innovative pharmaceutical companies, substantially all of their revenues may be at risk and therefore losing the patent case could end the company. As a result, there can be enormous pressure to settle Paragraph IV patent litigation. Such settlements typically involve the parties agreeing to a date of generic entry that is earlier than the expiration date of the patent at issue. In addition, a subset of settlements (~25 percent by the FTC’s definition) may also involve “reverse payments.”

Reverse payments are payments that flow from the patent holder (the brand company) to the alleged infringer (the generic company). These settlements are referred to as reverse payment settlements because in most other patent litigation settlements the payments flow in the opposite direction from the alleged infringer to the patent holder. Most other patent litigation, however, involves an alleged infringer that has entered the market and thus faces a potential damages claim. As such, it is not surprising that, while payments flow from the alleged infringer to the patent holder in most settlements of patent litigation, payments flow in the opposite direction in Paragraph IV litigation where there typically are no damages claims.

The FTC and private plaintiffs also refer to these settlements as “pay-for-delay” settlements, claiming that the brand company makes these payments in exchange for the generic company agreeing to a later entry date than it otherwise would have without the payment. The assumption is that without the payment, the branded and generic companies would agree on an entry date that is consistent with the brand company’s probability of winning the patent case were the case to be fully litigated. With the payment, it is alleged that the entry date is later than the expected entry date under litigation. Because payments from the patent holder to the patent challenger run the risk of causing anticompetitive harm to consumers, both the FTC and private plaintiffs have challenged the validity of these settlements.

The FTC and private plaintiffs have taken a broad view of what can constitute a reverse payment. In their view, a reverse payment is anything of value flowing from the brand company to the generic company other than the value associated with earlier generic entry. Plaintiffs frequently allege that payments are “hidden” within business deals included as part of the settlement of the patent litigation—i.e., plaintiffs allege that these deals provide the generic company with compensation that is worth more than the value of the goods or services it is providing in exchange. The FTC and private plaintiffs also allege that agreements by brand companies not to launch authorized generics during the 180-day exclusivity period represent reverse payments. Often such agreements take the form of an exclusive license to the generic company that prevents the brand company from selling a license to any other generic company and further prohibits the brand company from launching its own generic product. Without competition from an authorized generic, the generic challenger stands to earn larger profits in the 180-day exclusivity period, particularly if it is the only first filer able to compete in that period.

C. The Supreme Court Decision in FTC v. Actavis

When evaluating the merits of antitrust cases involving reverse payment settlements, courts adopted conflicting standards. In particular, the Second, Eleventh, and Federal Circuits adopted a “scope-of-the-patent” standard, concluding reverse payment settlements are legal as long as (1) the patent was not procured by fraud, (2) the patent litigation
was not objectively baseless, and (3) the settlement did not limit competition beyond the scope of the potential exclusionary potential of the patent. In contrast, the Third Circuit adopted a “presumptively unlawful” standard. It found that the “the finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as prima facie evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.”

This circuit split led the Supreme Court to grant cert in FTC v. Actavis in 2012. The Supreme Court subsequently rejected both the presumption of illegality adopted by the Third Circuit and the scope of the patent test adopted by the Second, Eleventh, and Federal Circuits. The Court instead adopted a rule of reason approach. In the majority opinion, the Court placed the burden on plaintiffs to show significant anticompetitive effects flowing from challenged agreements. Lower courts, therefore, will need to weigh the potential anticompetitive harm of a reverse payment settlement against any procompetitive benefits.

The Court invited antitrust scrutiny only for settlements involving “large, unexplained” payments from the patent holder to the alleged infringer. As described in the majority opinion, “The rationale behind a payment … cannot in every case be supported by traditional settlement considerations. The payment may instead provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market.”

The Court also concluded that patent issues need not necessarily be litigated as part of a rule of reason analysis. Instead it ruled that “[a] large, unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the patent’s validity.”

The Court, however, provided little guidance to lower courts as to how to apply a rule of reason approach. It instead left many important open questions including (1) how to allocate the evidentiary burdens, (2) what constitutes a “payment,” (3) what justifications for any “payment” are acceptable, (4) when a payment becomes “large enough to merit antitrust scrutiny,” and (5) the relevance of patent issues.

THE “ACTIVATING ACTAVIS” PROPOSED RULE OF REASON APPROACH

In their article “Activating Actavis,” Edlin et al. describe their interpretation of the Supreme Court’s Actavis decision and how a rule of reason approach should be approached by lower courts. The authors exclude many aspects of a traditional rule of reason approach from their proposed approach. In the authors’ view, there is no need to assess anticompetitive effects or market power or to define a relevant market. Instead, they interpret the Court’s decision as saying that “both anticompetitive effect and market power could be inferred from large reverse payments themselves.” Specifically, if the reverse payment is larger than the brand company’s avoided litigation costs plus the value to the brand company of any goods or services received from the generic company, the authors conclude that the payment delayed generic entry and harmed consumers.

Edlin et al. also interpret the Actavis decision as preventing defendants from raising issues of patent validity and infringement as liability defenses. In addition, they see no need for patent strength to be assessed when evaluating damages, even though a damages assessment requires a determination of the length of generic entry delay, thus implicitly assuming that absent the reverse payment the parties still would have settled the patent litigation rather than fully litigate it. Edlin et al. believe the size of the payment (or the “unexplained” portion of the payment) can be used to determine the length of delay—i.e., what the agreed-upon generic entry date would have been absent a payment, thus assuming there would have been a settlement. They would have the finder of fact compare the size of the (unexplained portion of the) payment to the difference between the brand company’s profits per year with and without generic competition. For example, if the brand company would earn $100 million more in profits per year without generic competition than it would earn with generic competition, and the payment was $200 million, then a lower bound estimate of the period of delay would be two years ($200 million/$100 million).

According to Edlin et al., there are essentially no legitimate justifications for reverse payments beyond avoided litigation costs (defined narrowly) and the value of goods and services provided by the generic company. While the authors acknowledge that “[t]he Court leaves the door open to other ‘justifications’ for a reverse payment,” they also state that the Court “is skeptical, and does not explicitly identify any.” The authors “encourage courts to restrict their attention to arguments that involve showing that the challenged settlement will lead to a longer period of competition, or stronger competition, than should be expected from either litigation or from an alternative settlement without the payment.” In other words, the authors propose that defendants need not only show that the payment was made for reasons other than delayed generic entry, but also that the payment resulted in an earlier entry and/or more intense competition as liability defenses.

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competition than would otherwise have occurred. They offer no explanation for why defendants should have to do more than simply show that the payment did not cause delay and thus had no anticompetitive effects.

According to Edlin et al., the plaintiffs’ burden to establish that the payment is large and unexplained requires only (1) valuing any consideration flowing from the patentee to the claimed infringer, and (2) showing that the value exceeds the patent holder’s avoided litigation costs. The authors then suggest the burden should shift to defendants to show, if applicable, that the payment can be explained by the value of goods, services, or other consideration provided by the generic company to the brand company. In order to justify this shift in burden, they state that “defendants are in possession of the relevant evidence about their side deals. Moreover, the complexity is the result of the defendants’ own actions.”

**DEFINITION OF THE “BUT-FOR” WORLD**

From an economic perspective, “Activating Actavis” is oversimplified because it ignores several real-world complexities surrounding the settlement of patent litigation in the pharmaceutical industry. Edlin et al. often discuss a “but-for” world involving settlement without a reverse payment and an earlier agreed-upon entry date.21 However, it is not at all clear that in all cases the parties to Paragraph IV patent litigation would be able to settle without the brand company making a payment to the generic company.

As many previous authors have described, when the parties have differing beliefs regarding the strength of the brand’s patent case, different information about how the market will evolve over time, capital constraints, and/or different discount rates, they may not be able to reach a settlement without a payment.22 The FTC’s own statistics indicate that the rate of settlement increased after the Eleventh Circuit adopted the “scope of the patent” test that gave settling parties the go-ahead to include reverse payments in their settlement agreements.23

If the parties would have litigated the case absent a payment, then there are two potential outcomes: (1) the generic company wins the litigation and enters soon after final judgment, and (2) the brand company wins and there is no entry prior to patent expiration. If, in the “but-for” world, the case would have been litigated and the brand would have won the litigation, then a settlement that allowed generic entry to occur prior to the expiration of the patent would not have delayed entry compared to when it would have occurred in the “but-for” world.24 In order to assess whether a reverse payment caused anticompetitive harm, it would seem necessary to determine whether the parties would have still settled the litigation absent a payment (no simple task) and, if not, what the outcome of the patent litigation would have been. Determining what the likely outcome of the patent litigation would have been clearly requires assessing patent validity and infringement issues—something Edlin et al. dismiss as completely unnecessary.

**JUSTIFICATIONS FOR REVERSE PAYMENTS IGNORED BY EDLIN ET AL.**

Despite Edlin et al.’s suggestion that reverse payments can only be justified by avoided litigation costs or the value of goods and services received, there are a number of other justifications for reverse payments. The presence of such justifications in any particular case is likely to involve a very fact-specific inquiry as is typical of rule of reason analyses.

The Supreme Court expressed concerns about payments that could not “be supported by traditional settlement considerations.” The question therefore becomes whether there are traditional settlement considerations that led to the payment. Traditional settlement considerations can encompass much more than narrowly defined avoided litigation costs (i.e., legal fees). The important thing to understand is that brand companies may be willing to make payments for a variety of reasons having nothing to do with delaying generic entry beyond the date consistent with the strength of their patent case. Below we discuss traditional settlement considerations that may explain reverse payments and have no anticompetitive implications. The key question when evaluating these considerations is whether they would have led the brand company to be willing to make a payment of the size observed while at the time agreeing to a generic entry date that is consistent with the strength of the brand’s patent case.25

**A. Risk Aversion**

A company and/or its management may be risk averse and prefer a certain outcome associated with settlement even if its expected value is lower than the uncertain outcome of litigation. Numerous studies have shown that individuals are willing to receive less than the expected outcome from a gamble to avoid the risk of the gamble.27 For example, given the choice of taking a gamble with a 50 percent chance of winning $100 and a 50 percent chance of winning nothing, or accepting $45 with certainty, many people will choose the $45, even though the expected payoff from the gamble is $50. The higher the stakes, the more likely a person will want the sure outcome—i.e., a person who might accept a 50-50 gamble involving $100 versus a $45
certain payout might instead choose the certain payout if the stakes were a $10 million gamble with an expected pay-off of $5 million versus a $4.5 million certain payoff. Indeed, a person might be willing to accept much less than $4.5 million in this situation.

A pharmaceutical company facing the loss of patent protection on an important product may be similarly risk averse. Consider, for example, a small pharmaceutical company with a single product that accounts for the bulk of its revenues. If the company loses the patent case, the managers and officers of the company may face the risk of job loss. Significant stock holdings or options in the company may also motivate them to avoid risk. In such a situation, even if the company believes it has a high probability of winning the patent case, the company would still have strong incentives to settle in order to avoid the small chance of losing the case. A reverse payment made under such circumstances need not reflect the company paying to eliminate the risk of competition. Instead, the company may be willing to make a payment and still accept an entry date consistent with its assessment of the likelihood it would win the case. In other words, the settlement does not eliminate or reduce the expected amount of competition.

For example, if a risk averse company believes it has a 95 percent chance of winning the patent case, it would be willing to accept an entry date that allows the generic to enter 95 percent into the remaining patent life and still make a payment to the generic company. The size of the payment could be quite large depending on how much value the company is willing to give up in order to gain certainty over its future revenues. The payment amount is likely to be larger, the larger the revenues at stake and the more important the drug is to the company’s portfolio of drugs. For example, in the reverse payment antitrust case involving the drug Niaspan, the drug accounted for over 50 percent of the branded drug manufacturer’s sales. Plaintiffs themselves agree that it was “bet-the-company” patent litigation.

It is important to note that generic companies are generally in a far better bargaining position than the branded company when it comes to settling Paragraph IV patent challenges. As already noted, generic companies are generally not at risk for damages and therefore have little to lose from fully litigating the case. Knowing this, generic companies are likely to be able to extract a far better deal in a settlement than is warranted by any weaknesses in the brand’s patent case. Under these circumstances, the fact that the generic is able to extract a payment from the branded does not make the deal anticompetitive.

B. Business Costs Associated with Uncertainty

Even absent risk aversion, there are costs associated with uncertainty that could result in a brand company being willing to make a payment while still agreeing to an entry date that is consistent with the expected entry date were the case to be fully litigated. Patent litigation increases the uncertainty associated with future revenue streams and such uncertainty may make it difficult for the brand company to make business decisions. For example, if a pharmaceutical company is unsure how much longer it will have patent protection for one of its drugs, that uncertainty will complicate any decision concerning whether the company should invest in research and development (R&D) on additional indications or new products using the patented technology. Indeed, it could lead to underinvestment in such R&D.

Furthermore, when faced with this uncertainty a pharmaceutical company might also underinvest in marketing the drug, as marketing efforts will benefit the generic drug once it is launched rather than the branded drug. These effects have real costs for pharmaceutical companies (and consumers). Even if the brand were to win the patent litigation, the underinvestment in R&D and marketing could reduce long-run sales of the product. In addition, patients may not benefit from knowing the drug works for additional indications or new products using the patented technology. Indeed, it could lead to underinvestment in such R&D.

Reverse payments can also be explained by the benefits branded companies receive from smoothing sales and revenue streams and avoiding costs associated disruptions to revenues. For example, disruption to revenues due to a patent litigation loss can mean that a company has to lay off part of its sales force and then hire a new sales force at a later point when new products are launched. Such efforts come at a cost. As a result, the costs associated with losing patent litigation are more than just the lost drug sales. Because the unexpected loss of patent protection involves costs beyond just the loss of revenues, a pharmaceutical company may be willing to make a payment to ensure patent protection through a certain date, even though the payment does not extend the generic entry date beyond the date that is consistent with the strength of its patent case. Edlin et al. do not take such costs into account, nor do

C. Costs Associated with Disruptions to Revenues

Reverse payments can also be explained by the benefits branded companies receive from smoothing sales and revenue streams and avoiding costs associated disruptions to revenues. For example, disruption to revenues due to a patent litigation loss can mean that a company has to lay off part of its sales force and then hire a new sales force at a later point when new products are launched. Such efforts come at a cost. As a result, the costs associated with losing patent litigation are more than just the lost drug sales. Because the unexpected loss of patent protection involves costs beyond just the loss of revenues, a pharmaceutical company may be willing to make a payment to ensure patent protection through a certain date, even though the payment does not extend the generic entry date beyond the date that is consistent with the strength of its patent case. Edlin et al. do not take such costs into account, nor do
they consider how such costs could lead a brand company to make a payment for reasons having nothing to do with delaying generic entry. One would expect to see payments in situations where losing the patent case would result in a substantial gap in the brand company’s product portfolio before the company is able to introduce a new product.

D. Irreparable Harm from At-Risk Entry

A brand company may also be willing to make a reverse payment while at the same time agreeing to a generic entry date consistent with the strength of its patent case in order to avoid the irreparable harm at-risk entry would cause. The Hatch-Waxman Act grants a 30-month stay of FDA approval when a brand company files a patent infringement suit following a Paragraph IV ANDA filing. Once that 30-month stay is over, the FDA can grant final approval allowing the generic to enter even if the patent litigation is not yet resolved. Such entry may cause irreparable harm to the brand company as a result of long-term negative effects on prices and formulary status, lost R&D opportunities, and loss of goodwill with consumers and physicians. Such harm is irreparable because it cannot be measured precisely and therefore cannot be the basis of a damages claim should the brand company win the patent case.

While the brand company can seek a preliminary injunction to prevent the generic from entering, the success of such a petition is generally far from certain. Faced with imminent generic competition, a brand company may be especially incentivized to settle a case, and such a settlement could easily involve a payment commensurate with the expected irreparable harm it would face from at-risk entry. Again, such a payment need not result in the agreed-upon generic entry date being later than the date that is consistent with the strength of the brand’s patent case.

Seeing settlements involving reverse payments around the time of the expiration of the 30-month stay is therefore not surprising. Such settlements may be particularly likely under certain circumstances—e.g., when the company is highly dependent on the sales from the challenged product to fund its current R&D efforts or when there are other competitors in the therapeutic class who may take the opportunity presented by an at-risk launch to negotiate rebate agreements with insurers to gain more favorable formulary status. Edlin et al. ignore these legitimate justifications for a brand company to agree to make a payment to the alleged infringer when settling Paragraph IV litigation. These justifications are consistent with traditional settlement considerations and need not be associated with an anticompetitive delay in generic entry.

VI. CONCLUSION

This article has highlighted two flaws of the Edlin et al. proposed approach to a rule of reason analysis of reverse payment settlements. The authors of “Activating Actavis” put forth a simple model that fails to account for important real-world complexities that both complicate the task of defining the “but-for” world and provide legitimate procompetitive justifications for reverse payments beyond those deemed acceptable by the authors.

In particular, Edlin et al. fail to consider that in a “but-for” world where no reverse payment is made, the parties might not have been able to reach a settlement. In such a “but-for” world, assessing the likely outcome of the patent case had it been fully litigated becomes key to understanding whether there was anticompetitive harm. For this reason alone, the authors’ conclusion that issues of patent validity and infringement need not be assessed is incorrect.

The authors also fail to account for numerous legitimate procompetitive justifications for reverse payments beyond avoided litigation costs or the value of goods and services received from the generic company. Such justifications may explain the reverse payment, but may be challenging to demonstrate. Whose burden it will be show whether such justifications explain a reverse payment will be a key issue for lower courts to decide. Furthermore, in the absence of good ways to quantify whether such justifications can explain a payment, the parties may instead want to approach the question of whether the payment caused an anticompetitive delay more directly by assessing whether the agreed-upon entry date was consistent with the strength of the brand company’s patent case. Such a strategy would also require addressing issues of patent validity and infringement.
ENDNOTES


3. Patent life is extended for half the period between when drugs enter human trials and when the new drug application (NDA) is submitted to the FDA and the entire period the NDA is being reviewed by the FDA, but not longer than five years.

4. Initially, the very first generic company to file a Paragraph IV challenge received the 180-day exclusivity, resulting in representatives from generic companies literally lining up outside FDA offices to be the first to hand in an ANDA on the first eligible filing date (i.e., four years after approval of the innovative drug). The 2003 Medicare Modernization Act amended the Hatch-Waxman Act such that generic companies filing on the same day are considered to have filed at the same time, resulting in multiple “first filers” who are eligible to share the 180 days of exclusivity.


6. For example, if there is a 50 percent chance of winning the patent case, the FTC believes that absent a reverse payment, the parties would settle on a generic entry date that splits the remaining patent life. The FTC’s concern is that by making a payment to the generic, the brand company is able to negotiate a generic entry date that keeps the generic out of the market for a longer period of time—e.g., 75 percent into the remaining patent life for the above example, rather than 50 percent. Note that the FTC does not appear to be concerned about payments that delay generic entry but not beyond the expected date of entry under litigation. This can be seen by the FTC’s acceptance of payments to avoid litigation costs. Absent the ability to make payments to avoid litigation costs, a brand company should be willing to accept a generic entry date that is earlier than the date consistent with the strength of its patent case—e.g., 45 percent into the remaining patent life in the above example. If litigation costs are an acceptable justification for a payment, then the issue is not simply whether the payment causes a delay in the “but-for” entry date, but whether it causes a delay beyond the expected date of entry were the case to be fully litigated. Finally, note that the entire premise of the FTC’s position is that brand and generic companies have precise and consistent estimates of the likelihood the brand will win the patent case. In reality, any assessment of the strength of the brand’s patent case is likely to be vague at best—e.g., more likely than not—rather than a precise number.

7. Note that in typical patent settlements where payments flow from the alleged infringer to the patent holder, those payments are often substantially below the potential damages award were the brand to win the patent litigation. In other words, the brand company forgives a portion of its potential damages award. It could be argued that forgiveness of damages constitutes an exchange of value from the patent holder to the alleged infringer and, if so, most settlements of patent litigation could be argued to involve “reverse” payments. In essence, this means that there is nothing particularly unusual about settlements of Paragraph IV litigation that involve payments from the patent holder to the alleged infringer.

8. Authorized generics are prescription drugs manufactured or licensed under the brand company’s NDA that are sold as generic drugs.

9. Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1312 (11th Cir. 2003); Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005); In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (2nd Cir. 2006); In re Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323 (Fed. Cir. 2008).


12. Ibid., p. 7. See also p. 16.


14. Ibid.

15. Ibid. By claiming there is no need to analyze competitive effects, Edlin et al. also implicitly assume there are no procompetitive benefits that could possibly balance against the higher prices consumers would face if generic entry were delayed. Such an assumption is not necessarily a valid one in all cases. See Henry Grabowski, Rahul Guha, Zoya Ivanova, Tracy Lewis, and Maria Salgado, “Does Generic Entry Always Increase Consumer Welfare?” Food and Drug Law Journal, Vol. 67, No. 3, 2012.


17. Ibid., p. 23, FN 52.

18. Class action plaintiffs may take a more aggressive stance on the date of “but-for” generic entry, including potentially suggesting the “but-for” date coincides with the expiration of the 30-month stay, a but-for trial date, or a date based on a comparison the generic company’s profits from entry versus the size of the payment.

19. “Activating Actavis,” p. 18. Edlin et al. cite to no statement made by the Court expressing such skepticism and indeed this statement appears to be based purely on the authors’ own skepticism that there might be other justifications.

20. Ibid., p. 20.

21. “Activating Actavis,” p. 16. Class action plaintiffs will likely take a far more aggressive approach and instead suggest there would have been at-risk entry at the end of 30-month stay or at the time of trial. However, at-risk entry cannot be assumed, as a generic company may choose not to enter at risk given that doing so opens it up to be sued for significant damages by the brand company. Furthermore, a preliminary injunction may have been granted by the court to the brand company.


23. Federal Trade Commission, “Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions;” January 2010, p. 9: “Over the FY2004 to FY2008 time period, the percentage of drugs that settled per year (not including injectables) increased from 7 percent to 18 percent, with most of the increase following the Eleventh Circuit’s Schering decision.”

24. This discussion ignores other benefits of settlements over litigation, such as reduced burden on and cost to the court system.

25. Almost all of the considerations can be recast as “litigation costs” in that they are costs or potential costs associated with fully litigating the patent case. The entire discussion that follows
assumes that brand companies are able to precisely estimate the likelihood of winning their patent case, an assumption underly-
ing the conclusions of Edlin et al., as well as the FTC, and class action plaintiffs in reverse payment cases. There is no basis for this assumption, however.


27. Risk aversion squarely fits within traditional settlement consider-


29. Edlin et al. acknowledge that “[a] sufficiently risk-averse patentee might in principle pay the defendant an amount in excess of avoided litigation costs and also agree to an entry so early that consumers enjoy more competition under the settlement than would be expected from litigation.” “Activating Actavis,” p. 20. The authors nevertheless argue that courts should reject risk aver-

sion arguments because “[t]he Court says that payments to avoid even a small risk of competition are antitrust violations. That is reason enough to deny a risk-aversion defense.” “Ibid. The authors’ reasoning is flawed for two reasons. First, the authors fail to note that making a payment while accept-

ing a generic entry consistent with the strength of the brand company’s patent case is not consistent with paying to avoid even a small risk of competition. Indeed, by accepting an entry date prior to patent expiration, the brand company is accepting the risk of competition. Second, the relevant question is whether the payment delays entry beyond the date consistent with the strength of the brand company’s patent case. If that were not the case, then avoided litigation costs would not be a legitimate justi-

fication for a reverse payment because, absent the ability to make a payment up to the amount of saved litigation costs, presumably the brand company would have been willing to accept an earlier entry date. Yet the Court, the FTC, and even class action plaintiffs (not to mention Edlin et al.) have clearly accepted avoided litigation costs as a procompetitive justification for a reverse payment precisely because such a payment need not delay generic entry relative to what would be expected were the case fully litigated. Edlin et al. ignore the inconsistency in their economic reasoning when it comes to risk aversion.

30. In re Niaspan Antitrust Litigation, United States District Court Eastern District of Pennsylvania, MDL No. 2460, Case No. 2:13-md-

2460 (JD), Consolidated Amended Class Action Complaint, Jan. 15, 2014, ¶165.

31. Ibid., ¶87.

32. The FTC and private plaintiffs would have the settling parties only bargain over the entry date, and disallow payments. However, because of the better bargaining position of generic companies, negotiating over entry date alone would likely result in an agreed-upon generic entry date that is earlier than the date consistent with the strength of the brand company’s patent case (assuming the parties are able to settle at all). Indeed, it could be substantial-

ly earlier, thus eroding the value of patents and reducing incentives for brand companies to conduct R&D into new drugs. Moreover, because the generic company does not gain as much from an earlier entry date as the brand company loses, it is not surprising that the settling parties prefer a payment over agreeing to an entry date that is earlier than warranted by the strength of the brand company’s patent case. It is a far more efficient way for the brand company to compensate for a weak bargaining position resulting from risk aversion or any of the other traditional settle-

ment considerations discussed below.

33. Uncertainty as to the outcome of patent litigation may reduce a pharmaceutical company’s ability to obtain funding to make such investments.

34. Note that this harm is separate from the lost sales it would expect from a-risk generic entry which are more easily ascertainable.

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