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# **ACTIVATING *ACTAVIS*: ECONOMIC ISSUES IN APPLYING THE RULE OF REASON TO REVERSE PAYMENT SETTLEMENTS**

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## **Activating Actavis: Economic Issues in Applying the Rule of Reason to Reverse Payment Settlements**

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### **I. Introduction**

In *FTC v. Actavis, Inc.*,<sup>3</sup> the Supreme Court reversed the Eleventh Circuit's decision, rejecting the so-called scope-of-the-patent test for reverse payment settlements in Hatch-Waxman pharmaceutical litigation. It also rejected the Federal Trade Commission and Third Circuit's arguments for presumptive illegality of reverse payments, declaring that the rule of reason is the appropriate framework in which to evaluate such settlements. In arguments before the Supreme Court, Actavis supported the scope-of-the-patent test, which would have insulated most reverse payment settlements from antitrust scrutiny, while the FTC argued that reverse payments should be presumptively unlawful. In declaring that the rule of reason should govern the antitrust analysis of reverse payment settlements, the Supreme Court explicitly rejected the arguments of both parties.

Proponents of the scope-of-the-patent test focus on the patentee's right, under patent law, to exclude others. They argue, therefore, that reverse payment settlements should be presumed to be lawful as long as the settlement does not impose competitive restraints that go beyond the scope of the patent. On the other hand, those who advocate that reverse payment settlements should be considered presumptively unlawful maintain that such settlements nearly always have anticompetitive effects. In fact, reverse payments have the potential both to harm and to benefit consumers. Consequently, the scope-of-the-patent test is likely to allow some settlements that are in fact anticompetitive, while treating reverse payments as presumptively illegal is likely to prevent some settlements that are procompetitive or competitively neutral. The Supreme Court rightly rejected both approaches and mandated that lower courts take a more nuanced approach, analyzing reverse payment settlements under the rule of reason.

In doing so, the Court provided little guidance on how such analyses should be carried out, leaving it to lower courts to develop the analytical framework in which to assess these settlement agreements. In this article, we discuss the economic and legal underpinnings of the relevant issues and offer some guidance on the key economic questions that lower courts will need to assess as they proceed under the rule of reason.

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<sup>3</sup> *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

## II. Brief Overview of the Competing Positions and the Court's Ruling

### A. The FTC's Argument that Reverse Payment Settlements Should be Presumptively Unlawful

The FTC argued for both a per se rule and a quick-look approach to reverse settlements. The FTC's primary argument was that reverse-payment agreements should be treated as presumptively unlawful because they are similar to unlawful horizontal restraints of trade.<sup>4</sup> Specifically, the FTC contended that reverse payments have the anticompetitive effect of "[r]aising price, reducing output, and dividing markets."<sup>5</sup>

The FTC aimed that the patentee has the ability and the incentive to pay the would-be generic entrant more than the generic firm would have earned if it had entered into the market:

In the pharmaceutical industry . . . standard economic theory predicts that a brand-name manufacturer's monopoly profits will greatly exceed the combined profits that the brand-name and generic manufacturers could earn if they competed against each other for sales of the same drug. The brand-name manufacturer's monopoly profits are large enough to pay its would-be generic competitors more than they could hope to earn if they entered the market, while still leaving the brand-name manufacturer greater profits than it could earn in the face of generic competition.<sup>6</sup>

The FTC went on to argue that "[i]n substance, a reverse-payment agreement is a mechanism for inducing the generic manufacturer to forgo its own output, as a way to increase the manufacturers' combined profits, at the expense of competition and consumer welfare."<sup>7</sup>

The FTC argued for the application of a quick-look approach to reverse payments because the respondents' conduct closely resembles conduct that is usually or almost always harmful to competition. Under this approach, the agreement would be presumed anticompetitive and the defendant would have the burden of providing procompetitive justifications for the conduct.<sup>8</sup> The FTC contended that because both parties benefit from monopolistic pricing, there is a strong incentive to prolong the period of the brand name's exclusivity.<sup>9</sup> A quick look test is also administratively efficient because it would not require a full evaluation of the scope of the patent and would obviate the need for a costly patent trial within an antitrust trial.

Acknowledging that public policy generally favors settlements, the FTC argued that reverse payments are an exception because of their tendency to reduce competition. Moreover,

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<sup>4</sup> Brief for the Petitioner at 15, *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 267027.

<sup>5</sup> *Id.* at 20 (citing *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 777 (1999)).

<sup>6</sup> *Id.* at 21.

<sup>7</sup> *Id.* at 23.

<sup>8</sup> *Id.* at 33 (citing *Cal. Dental*, 526 U.S. at 771).

<sup>9</sup> *Id.* at 34–36.

the FTC argued that the scope of the patent test ignores the strength of the patent involved. Further, the FTC looked to the legislative history of the Hatch-Waxman Act to show that Congress intended to promote rapid and timely entry of generics into brand-name drug markets.<sup>10</sup> In the FTC's view, these goals and purposes would be frustrated if reverse payments were routinely allowed to delay generic entry into the market.<sup>11</sup>

## **B. Actavis Argued for the Scope-of-the-Patent Test**

Actavis argued against the Government's proposed "quick look" test.<sup>12</sup> Primarily Actavis argued that the government had not shown that reverse payments result in "'obvious' and 'actual[] anticompetitive effects,'"<sup>13</sup> citing studies that indicate that reverse payments are not always, or even usually, anticompetitive.<sup>14</sup>

Further, according to Actavis, the Government's proposed rule does not take into account the patent holder's lawful right to exclude competitors.<sup>15</sup> Actavis believes that its patent gives it the unqualified right to exclude all competition through any means it finds necessary, so long as the settlement does not exceed the scope of the patent in either length or breadth of the patent's terms. Such means, of course, include reverse-payment settlements of patent infringement suits.<sup>16</sup>

Actavis also argued that the Government's "quick look" rule would result in unintended consequences.<sup>17</sup> Such a rule would chill settlements and induce lengthy and costly litigation.<sup>18</sup> Moreover, Actavis contended that the Government's rule is so ambiguous that it would cause confusion in the industry that would deter the innovation and research that leads to new drugs and would limit the number of paragraph IV patent challenges by generic pharmaceutical companies.<sup>19</sup>

## **C. Analytical Problems with the Government's Quick Look Approach**

The FTC's desire for a quick look approach is likely to result in many decisions that condemn procompetitive outcomes or dramatically deter the consummation of procompetitive transactions. Reverse payments may, under certain circumstances, (1) encourage generic ANDA

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<sup>10</sup> *Id.* at 3, 30–32. "The Hatch-Waxman Amendments reflect a strong congressional policy that favors testing the scope and validity of pharmaceutical patents, with a view to realizing the benefits of generic competition at the earliest appropriate time." *Id.* at 30–31 (citing C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1614 (2006)).

<sup>11</sup> *Id.* at 30–32.

<sup>12</sup> Brief for Respondent Actavis, Inc. at 16, *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 662705.

<sup>13</sup> *Id.* at 13 (citing *Cal. Dental*, 526 U.S. at 771, 775 n.12).

<sup>14</sup> *Id.* at 23–25.

<sup>15</sup> *Id.* at 19–20.

<sup>16</sup> *Id.* at 12–13.

<sup>17</sup> *Id.* at 39.

<sup>18</sup> *Id.* at 39–40.

<sup>19</sup> *Id.* at 40.

filings, (2) allow generic entry earlier than would have occurred if the patent had been litigated, (3) protect valid pharmaceutical patents from infringement, (4) avoid high or excessive litigation costs, and (5) facilitate bona fide side deals. Thus, reverse payment settlements may enhance efficiency and benefit consumers.<sup>20</sup>

Addanki and Daskin outline some of the flaws in the FTC's argument. They consider a hypothetical patent suit in which the objective probability that either party will win the litigation is 0.5 (i.e., a fifty percent chance for each party).<sup>21</sup> Assume, for simplicity, that discovery is complete and that the outcome of the trial will be known quickly. In that case, the expected date of generic entry under litigation would be half the time left until the expiration of the patent.<sup>22</sup> It might seem, therefore, that both parties would be willing to settle the litigation, without any side payments, by agreeing that the generic will enter at that date: if the patent runs for another ten years, the parties should be willing to settle the dispute by agreeing that the generic will enter in five years. Moreover, it might seem that the parties could not agree on any *other* date of entry: the patentee would not agree to earlier entry, and the generic firm would not agree to delay entry until a later date. In such circumstances, the FTC apparently believes that a pure term-split settlement, in which the parties agree that the generic will enter at that date, is the appropriate settlement. The Commission seems to believe that any payment from the brand-name manufacturer to the generic manufacturer is effectively a payoff or bribe to delay generic entry beyond the date of such a (hypothetical) pure term split.<sup>23</sup>

In fact, the FTC's argument is overly simplistic. For one thing, a pure term-split settlement may not be feasible. While the objective probability that either party will win the suit may be 0.5 (fifty percent), each party may be somewhat more optimistic about its chances; in formal terms, their *subjective* probabilities may diverge from the *objective* probabilities. The patentee (brand-name pharmaceutical company), for example, may believe that it has a sixty percent chance (i.e., a probability of 0.6) of prevailing, while the would-be generic entrant may think that the patentee has only a forty percent chance of prevailing (i.e., a probability of 0.4). If each party then bases its settlement strategies on its view of the (statistically) *expected* outcome of the litigation, the patentee would not agree to allow generic entry in less than six years, and the generic firm would not agree to wait more than four years before entering. Neither party, it would seem, would agree to settle for entry at any time between four and six years. In short, a pure term split would not be feasible.

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<sup>20</sup> For another opinion on why the FTC's proposed quick look is the wrong approach, see Sumanth Addanki, Alan J. Daskin & Christine S. Meyer, *High Court Brings Economics Back To Pay-For-Delay Analysis*, LAW360 (June 17, 2013), available at [http://www.nera.com/nera-files/PUB\\_Law360\\_PayforDelay\\_0613.pdf](http://www.nera.com/nera-files/PUB_Law360_PayforDelay_0613.pdf). The paper concludes that "a settlement with a reverse payment may in fact allow for entry earlier than might be expected with continued litigation, thus benefiting consumers." *Id.* at \*3.

<sup>21</sup> The argument in the text does not hinge on the parties' having equal probabilities of success in the litigation. In the discussion above, we assume equal probabilities for simplicity only.

<sup>22</sup> Another way of stating this is that "[l]itigation, therefore, represents a lottery with two possible outcomes; the value of the lottery to each firm is simply the mathematical expected value—the probability-weighted average—of the values of the two outcomes." Sumanth Addanki & Alan J. Daskin, *Patent Settlement Agreements*, in 3 ABA SECTION OF ANTITRUST LAW, ISSUES IN COMPETITION LAW AND POLICY 2127, 2133 (2008).

<sup>23</sup> *Id.* at 2130–31.

In reality, however, both parties may consider more than simply the expected outcome under litigation. If, as is often the case, the patentee earns a substantial fraction of its profits from the pharmaceutical in question, it might be particularly concerned about an unfavorable outcome: if it loses the litigation, the generic firm will enter immediately and the brand-name firm's profits will plummet. In formal terms, the patentee may be risk-averse. If so, the brand-name firm might be willing to agree to generic entry in, say, four and a half (4.5) years. The certainty that generic entry will not be even earlier—in the extreme, as soon as the trial ends—may compensate for the fact that the generic will enter at a date that is earlier than the expected date under litigation.<sup>24</sup>

Even so, the generic firm might still be unwilling to wait more than four years. If so, a pure term-split settlement would still not be feasible. In that case, however, the patentee might be willing to offer the would-be entrant a payment to induce it to accept a settlement with entry after four and a half years. If the parties do in fact agree to such a settlement, (i) there is a so-called reverse payment (from the patentee to the potential infringer), but (ii) entry will be *earlier* than the (objective) expected date of entry under litigation; so consumers will be *better* off than they would have been had the parties proceeded with the litigation.<sup>25</sup>

Even if the parties' subjective probabilities do coincide with the objective probabilities, a reverse-payment settlement may be procompetitive. If the parties agree that there is a fifty percent chance that either will prevail, the patentee, because of risk aversion, may prefer certain entry after, say, four years to expected—but uncertain—entry after five years if the parties litigate their dispute. The generic firm, of course, would also prefer to enter in four years rather than five. But if the would-be entrant has limited liquidity, it might not be able to wait that long; after all, until it enters, it earns no profits on the product. Again, a payment by the patentee to the generic firm may make it feasible for the parties to agree to a settlement in which the generic enters four years from now. In this case, too, there is a reverse payment, but consumers benefit from the settlement: generic entry occurs in four years, one year earlier than expected under litigation.<sup>26</sup>

The real world, therefore, is considerably more complicated than the simplistic world in which reverse payments necessarily imply competitive harm. Although previous commentators have advocated for rules similar to the FTC's quick look, a fact-based inquiry into the particular details of the settlement in question is required to analyze the competitive implication of an agreement.<sup>27</sup>

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<sup>24</sup> Recall that the *expected* date is a probability-weighted average of the possible dates of entry (in this case, a probability-weighted average of entry immediately and entry at the expiration of the patent).

<sup>25</sup> The Supreme Court briefly considers the possible implications of risk aversion and then brushes the concern aside without any substantive discussion. *See* *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236 (2013) (“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.”).

<sup>26</sup> See Addanki & Daskin, *supra* note 22, for further discussion of these and related issues, including the parties' potentially differing discount rates and views of future market developments.

<sup>27</sup> Many commentators have advocated for a rule that assumes harm. *See* Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1759–60 (2003) (arguing for presumptive illegality of patent settlements designed to delay entry, which in

## D. The Court Seizes the Middle Ground

In *Actavis*, the Supreme Court adopted the rule of reason for reverse payment settlements—and, in doing so, rejected the primary arguments of both the FTC and Actavis.

With respect to the FTC’s arguments, the Court stated: “The FTC urges us to hold that reverse payment settlement agreements are presumptively unlawful and that courts reviewing such agreements should proceed via a ‘quick look’ approach rather than applying a ‘rule of reason.’ . . . . We decline to do so.”<sup>28</sup>

The Court also explicitly rejected the scope-of-the-patent test championed by Actavis and other pharmaceutical manufacturers. Had the Court endorsed the scope-of-the-patent test, the FTC effectively would have lost any ability to file suit against such settlements. The resulting rule allows the FTC to investigate and selectively enforce cases against reverse payments.

The Court sets forth several examples of how reverse payments can harm and have harmed consumers by preventing competition on the merits and deterring the entry of generic drugs.<sup>29</sup> The Court notes that reverse payments may, in some circumstances, facilitate horizontal collusion between competitors or potential competitors in the same market. Thus, the scope-of-the-patent test might have immunized some settlements that [would have] harmed consumers.

The Court lists five reasons why the FTC should be able to present its full antitrust case under the rule of reason. Reverse payments (1) have the “potential for genuine adverse effects on competition”, but (2) concerns about such effects will “sometimes prove unjustified”; (3) “where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely “possesses the power to bring that harm about in practice.” Moreover, (4) the rule of reason is administratively feasible for courts, and (5) the possibility of antitrust liability does not prevent the parties from settling their dispute.<sup>30</sup>

## III. “Structuring” the Rule of Reason Analysis of Reverse Payment Settlements

As it often does, the Court “leave[s] to the lower courts the *structuring* of the present rule-of-reason antitrust litigation.”<sup>31</sup> Nevertheless, the Court does indicate some areas that it thinks the district courts should focus on:

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an antitrust context would automatically shift the initial burden to the defendant to provide procompetitive justifications of the conduct). *See also* Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 785 (2002) (arguing that district courts should consider preliminary injunctions and, if they then deny one, apply the quick look rule of reason, as the settlement is then usually anticompetitive).

<sup>28</sup> *Actavis*, 133 S. Ct. at 2237.

<sup>29</sup> *Id.* at 2232.

<sup>30</sup> *Id.* at 2234–37.

<sup>31</sup> *Id.* at 2238 (“[T]rial courts can structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences.”). *See, e.g.*, Leegin Creative Leather

[T]he 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 any other convincing justification. The existence and degree of any anticompetitive consequence may also vary as among industries.<sup>32</sup>

In this section, we provide some commentary on some of the issues that the courts should consider in a rule of reason analysis of reverse payment settlements.

### A. Monopoly Power

Any rule of reason analysis has to begin with a monopoly power screen. Without some showing that the brand-name firm has monopoly power in a relevant antitrust market, a reverse payment could not have anticompetitive effects.<sup>33</sup> Moreover, proper delineation of the relevant market is not always as obvious or straightforward as it might seem. In some cases, the brand-name pharmaceutical may indeed be able to charge a premium price because there are no good therapeutic alternatives to constrain its pricing of the drug. In that case, the molecule sold by the brand-name firm may constitute the relevant market, and the brand-name firm may have monopoly power.

In other cases, however, there may be numerous therapeutic alternatives to the brand firm's product. In such cases, any price premium that the brand-name product enjoys may reflect nothing more than a return on the firm's advertising, medical detailing, and similar efforts. If so, the relevant market at issue likely extends beyond the molecule sold by the brand-name firm, and the firm does not have monopoly power. In such a case, no further analysis is needed; the agreement is not likely to be anti-competitive.

It is worth noting in this connection that the FTC has, in the past, suggested that *any* branded drug represents a relevant market in its own right. In effect, the FTC's (and many private plaintiffs') argument runs as follows: typically, a generic entrant can take substantial sales from the incumbent branded drug and the average price falls significantly after entry, which, according to the FTC, is "direct evidence" that the incumbent must have possessed monopoly power prior to the entry.

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Prods., Inc. v. PSKS, Inc., 551 U.S. 877, 898 (2007). The Supreme Court explained that "[a]s courts gain experience considering the effects of these restraints by applying the rule of reason over the course of decisions, they can establish the litigation structure to ensure the rule operates to eliminate anticompetitive restraints from the market and to provide more guidance to businesses."

<sup>32</sup> *Actavis*, 133 S. Ct. at 2237.

<sup>33</sup> Henry N. Butler & Jeffrey P. Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57, 116 (2010) [hereinafter Butler & Jarosch]. See also Addanki & Daskin, *supra* note 22, at 2136 ("If there is no monopoly power present, there is no need for any further inquiry; the agreement could not be anticompetitive in its effect.").

While this argument may appear to have some superficial intuitive appeal, it is unusable in the world of pharmaceuticals, because it entirely overlooks the institutional characteristics of the pharmaceutical industry, in particular, the nature of competition from “AB-Rated Generics.” To see this, consider two polar cases of generic entry. In the first case, assume that the branded drug confers genuine therapeutic advantages over any existing formulation, supporting a premium price for that drug. Once practitioners are made aware of these advantages, the therapeutic benefits will sustain the price premium as long as no equivalent substitute product is available. As noted above, under these conditions the branded drug could have monopoly power (although, of course, the inquiry would not stop there).

In the second case, consider a branded drug that confers no material therapeutic benefit over existing alternatives, but whose patent covers an alternative (technically unique) delivery mechanism, which can be exploited by creative marketing and brand-building activities; any price premium depends entirely on the brand awareness created by advertising and marketing efforts. This is little different from branded white bread being more expensive than a private label of equal or even greater objective quality: the premium is not a reflection of monopoly power, but is merely the economic return to advertising/promotional efforts. The problem is that the effects of AB-rated generic entry will be similar enough that the FTC’s so-called “direct test” will not be able to distinguish these two polar cases. The first drug will continue to be prescribed for its benefits (as long as no other branded substitutes are available) and substitution laws will ensure that (a) the generic will be dispensed in place of the brand and (b) that the average price paid will fall as a result. In the second case, too, prescriptions written for the brand will be filled with the generic, again resulting in reduced average prices. In both cases, therefore, the conclusion will be that there was monopoly power enjoyed by the brand, which is obviously incorrect.

## **B. Did the Patentee Actually Make a Reverse Payment?**

In some cases, what looks like a reverse payment may be nothing of the sort. Pharmaceutical companies often enter into multiple agreements at the same time. While settling on a mutually agreeable date for generic entry, for example, the brand-name firm may buy from the generic firm the right to sell a different drug. If so, a payment will flow from the patentee to the generic firm, but there can be no presumption that it is a reverse payment: that payment does not necessarily have anything to do with the settlement of the patent infringement suit.<sup>34</sup> To be sure, if the patentee pays an artificially inflated price for the right to sell the second drug, the payment may be designed to conceal what is in fact a reverse payment. But a fact-based inquiry would be required to establish that fact.<sup>35</sup>

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<sup>34</sup> C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 641 (2009) (“If settlement and delay occur as part of a larger set of transactions between the two firms, how do we know that the payment was made in exchange for delay, rather than for some other valuable consideration? Often, this is a difficult question.”).

<sup>35</sup> Kenneth Glazer & Jenée Desmond-Harris, *Reverse Payments: Hard Cases Even Under Good Law*, ANTITRUST, Spring 2010, at 14, 19 (“Just because a thing of value was given to the generic company does not necessarily mean that that thing of value was in return for an agreement to delay. The nexus would still need to be shown.”).

In *Actavis*, the Court clearly recognized the need for consideration of the possibility that the alleged reverse payment is not anticompetitive:

The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement. That payment may reflect compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item. There may be other justifications. Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement. In such cases, the parties may have provided for a reverse payment without having sought or brought about the anticompetitive consequences we mentioned above. But that possibility does not justify dismissing the FTC’s complaint. An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.<sup>36</sup>

The Court’s recognition that some payments that appear to be reverse payments are, in fact, not payments that might lead to concern about anticompetitive effects is an important justification for applying the rule of reason to the entire category of transactions.

### **C. The Size of the Reverse Payment, Market Power, and Anticompetitive Effects**

In *Actavis*, the Court suggested a shortcut for proving market power:

At least, 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. An important patent itself helps to assure such power. Neither is a firm without that power likely to pay “large sums” to induce “others to stay out of its market.” In any event, the Commission has referred to studies showing that reverse payment agreements are associated with the presence of higher-than-competitive profits—a strong indication of market power.<sup>37</sup>

The relative size of the reverse payment can be an indicator of the anticompetitive nature of the deal. As a matter of economics, the Supreme Court placed unwarranted emphasis on this factor, but under certain conditions it can be an indicator of harm. Those conditions include (1) settlements where the payment makes up a large portion of the patent holder’s monopoly rents, (2) where the generic is being paid more than it would make from entry into the market, and (3)

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<sup>36</sup> *Actavis*, 133 S. Ct. at 2236.

<sup>37</sup> *Id.* (citations omitted).

where the payment is significantly larger than the costs of litigation.<sup>38</sup> However, this indicator is not a substitute for proof of monopoly power.

#### D. Considerations of Patent Strength

One essential element of the rule of reason inquiry is to evaluate, at least to a first approximation, the likelihood of success in the patent infringement suit.<sup>39</sup> This may involve consideration of traditional doctrinal patent requirements such as newness, non-obviousness, the level of scrutiny that the PTO gave the patent, and the result of past litigation over the patent.<sup>40</sup> When the patent is considered strong, there is a higher likelihood that the patent holder would have prevailed at trial, making the settlement procompetitive or benign. A weak patent may indicate that any settlement is anticompetitive.<sup>41</sup>

Many commentators, lawyers, and agency sources have reluctantly agreed that a comprehensive antitrust examination requires an evaluation of patent strength. Carl Shapiro has written that,

[T]o compare consumer surplus under a settlement with consumer surplus from ongoing litigation requires an informed judgment as to the strength of the patent(s) at issue. If the patent is very strong, i.e., very likely to be found valid and infringed and difficult to invent around, the challenger is unlikely to offer much independent competition to the patentholder if litigation proceeds.<sup>42</sup>

He concludes that “there does not appear to be any way around the need to assess patent strength directly if one is trying to determine whether a settlement benefits consumers.”<sup>43</sup> At one time the DOJ also supported this position.<sup>44</sup> The DOJ, however, flipped its view and supported instead the quick look approach in the *Arkansas Carpenters* case.<sup>45</sup>

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<sup>38</sup> See Butler & Jarosch, *supra* note 33, at 117–18 (reverse payments that set arbitrary numerical limits do not accurately reflect a sound economic rule of reason approach.).

<sup>39</sup> Addanki & Daskin, *supra* note 22, at 2137.

<sup>40</sup> As one example, consider the facts of *Tamoxifen*, where the patent at issue had already been invalidated by a district court and the settlement revoked that invalidation through the use of vacatur. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 194 (2d Cir. 2006). A challenge to the settlement could likely presume a very weak patent since the issue had already been litigated.

<sup>41</sup> Addanki & Daskin, *supra* note 22, at 2137. Addanki and Daskin go on to indicate that this does not mean that there needs to be a complete patent validity lawsuit. They contend that the court would need to determine “the *objective* odds that each party will prevail in the litigation, *not* the parties’ *subjective* estimates of those odds . . . . [I]t is not generally necessary to estimate those odds with tremendous precision.” *Id.*

<sup>42</sup> Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 397 (2003).

<sup>43</sup> *Id.*

<sup>44</sup> See Brief for the United States as Amicus Curiae at 13, *Joblove v. Barr Labs., Inc.*, 549 U.S. 1277 (2007) (No. 06-830).

<sup>45</sup> See Butler & Jarosch, *supra* note 33, at 86, n.181 (quoting Brief for the United States in Response to the Court’s Invitation at 10, *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010)).

Although a complicated inquiry, this result is required and supported by the court’s opinion because the anticompetitive nature of reverse payments is not at all obvious from a mere quick look. As Addanki and Daskin, in an apparently counter-intuitive insight, have articulated:

Agreements that involve reverse payments may, in fact, be procompetitive relative to litigation, while apparently innocuous agreements that involve no such payments may, in fact, be anticompetitive relative to the litigation alternative. There is, therefore, no substitute for closer, fact-specific analysis of the agreement and its context.<sup>46</sup>

This reasoning emphasizes that—unlike what the Court believes—the rule of reason is almost never efficient. Determining the likely competitive effects in a market and the outcome any settlement will have on consumers is inherently difficult and requiring of a detailed and extended analysis into market factors. Reverse payments, especially as they are burdened by undetermined and complicated questions of patent strength and validity, are certainly no exception.

That being said, the burden in the antitrust inquiry may be much lower than many commentators—including the FTC—have suggested. That is because for every such settlement agreement, there is a federal judge who has acquired considerable knowledge of the merits of the underlying patent case and, more often than not, has construed the claims of the patent in a *Markman* ruling. It seems entirely likely that a judge in that position has more than enough information about the underlying patent suit to have an informed judgment of the strength of the patent, certainly enough to be able to judge—aided by expert analysis if necessary—whether a given settlement of that suit is likely to benefit consumers.

### **E. Competitive Effects—Beyond Prices**

Assuming that monopoly power exists, the appropriate antitrust test then becomes an inquiry into competitive effects to determine “whether customers are better off under the settlement than they would have been (in expected terms) under litigation” which is to ask “whether the settlement resulted in an agreed-upon entry date later than what might have been expected under litigation.”<sup>47</sup>

What motivates the concern about generic entry dates is, of course, the expectation that prices will fall upon generic entry and, obviously, earlier entry usually results in lower prices. However, it is important to recognize that lower price is not a perfect indicator of consumer welfare. Lower prices caused by generic entry destroy the name brand manufacturer’s incentive to invest in advertising and other marketing activities that provide valuable information to physicians and their patients. The result could be (and often is) reduced sales of the drug at the lower prices because many doctors and patients will not be made aware of the benefits of the drug.

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<sup>46</sup> Addanki & Daskin, *supra* note 22, at 2138.

<sup>47</sup> *Id.* at 2136.

#### **IV. Conclusion**

Ever since the Eleventh Circuit first articulated its scope-of-the-patent test, the debate about reverse payment settlements has been strident and polarized. In effect, each side of that disagreement has urged that these settlements presumptively are either legal or illegal. In fact, however, there is no economic support for either extreme position. In choosing the middle ground by ruling that the settlements are properly analyzed under the rule of reason, the Supreme Court has rightly affirmed that whether or not a given settlement is anticompetitive, procompetitive or competitively neutral is ultimately a fact-specific inquiry. Some of the factors that will inevitably need to be addressed in such analyses include monopoly power, the characteristics and strength of the patent(s) at issue, the extent of the reverse payment, if any, the likely effect of the agreement on output and prices, and other considerations that often enter into rule-of-reason inquiries. Although such analyses can be burdensome and time consuming in some cases, in other situations threshold questions about monopoly power and patent strength may well prove pivotal and thereby obviate the need for an extended, full-blown rule of reason case.