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Measuring Reverse Payments in the Wake of *Actavis*

BY WILLIAM O. KERR AND CLEVE B. TYLER

IN *FTC V. ACTAVIS, INC.*, THE SUPREME Court addressed the antitrust implications of reverse-payment settlements of patent infringement litigation between branded and generic pharmaceutical companies.[1] For almost two decades the Federal Trade Commission and private antitrust plaintiffs pursued, with little success, litigation against entities involved in reverse-payment settlement agreements. However, recent successes for plaintiffs challenging reverse-payment settlements created a split among the circuits, leading the Supreme Court to address the lawfulness of such settlements.

A reverse-payment case involves settlement of patent litigation between a generic pharmaceutical manufacturer seeking to introduce a generic version of a patented product and the branded manufacturer who holds the patent. Under the terms of a settlement, the generic manufacturer typically agrees not to enter the market for a defined period, even if FDA approval is received for the product. In exchange, the branded manufacturer agrees to allow the generic to enter the market at some time before the expiration of the patent. The patent settlement is also generally part of a complex set of ancillary agreements that provide cash or other consideration to the generic manufacturer in full or partial compensation for services, products, or intellectual property rights provided to the branded manufacturer.

Settling parties have argued and some courts have found that, as long as a settlement agreement did not improperly attempt to extend the scope or term of the patent, the agreement was presumed to be immune from antitrust challenge, regardless of whether a potential generic entrant received other benefits from the branded producer as a result of ancillary agreements.[2] In contrast, the FTC and private antitrust plaintiffs have argued that any payment to a potential generic entrant constitutes compensation for delaying the generic's entry, and that reverse-payment settlements should be presumed anticompetitive. In 2012, the Third Circuit agreed, setting up the conflict among the circuits.[3]

William O. Kerr is a Director at Berkeley Research Group in Washington, D.C. Cleve B. Tyler is a Principal at Berkeley Research Group in Washington, D.C. Dr. Kerr served as an economic expert for the settling parties in the antitrust K-Dur litigation involving the FTC and private plaintiffs, and both Dr. Kerr and Dr. Tyler have consulted on antitrust issues related to a number of reverse-payment settlements.

The *Actavis* decision has resolved these competing views. In overturning the Eleventh Circuit, the Supreme Court held that a settlement with a reverse payment had the potential for being anticompetitive even if it did not expand the scope of the patent, and therefore antitrust plaintiffs should be able to challenge such settlements. The court ruled that plaintiffs could succeed in a challenge if they could show that a settlement included large payments to the potential entrant that could not be explained or justified by the value conveyed to the patentee in ancillary agreements or by other factors.

The *Actavis* Court did not hold that reverse-payment settlements should be presumed unlawful as the FTC wanted (and as the Third Circuit had done). Instead, following *Actavis*, the evaluation of an antitrust challenge to a reverse-payment settlement follows a rule-of-reason analysis. The Court ruled that antitrust enforcers and private plaintiffs should be given the opportunity to prove that a challenged agreement is anticompetitive by showing that the payment to the generic, or a significant portion of it, constituted a payment for delayed entry. In particular, the ruling reasons that a large and unjustified net payment to a generic can create an inference that a reverse-payment settlement is anticompetitive.

In focusing on the payment alone, the economic analysis apparently contemplated by the Court avoids direct consideration of the anticompetitive effects of a settlement, however. The potential anticompetitive effects of a reverse-payment settlement flow not from the payment itself, but instead from the prospect that with a settlement, consumers would face higher prices for the branded product for a longer period than if litigation continued and patent protection ended.[4]

To determine directly whether the period of protection is extended by a settlement, it would be necessary to assess the likely market outcome absent the settlement. The entry date for the generic specified in a typical settlement is earlier than the entry date if the patentee were to prevail in the patent litigation and patent protection were to continue until expiration. However, this generic entry date specified in the settlement is later than the entry date if the generic were to prevail in the patent litigation or if the generic entered at-risk

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upon receipt of FDA approval before the patent litigation is resolved. Whether or not a settlement extends the patent (and therefore anticompetitive effects result from a settlement) is a function of the strength of the patent, the corresponding probability that the patentee would have prevailed in the underlying litigation, and the related likely date of entry for the generic. The size and nature of the reverse payment bears only an indirect, and unpredictable, relationship to the probability of the outcome of the underlying litigation.

Settling parties in challenged cases have emphasized the need to focus on the underlying patent litigation, and the Eleventh Circuit and other courts have agreed. The parties have argued that, without an extensive analysis of the facts of the underlying patent case, it is not possible to determine if a delay in entry actually occurred. Lower courts sustaining the settling parties' position consistently have noted that to rule differently would be to require an impractical litigation of a patent case within the context of an antitrust case.

The Court recognized this argument as one basis for the Eleventh Circuit's opinion that such a ruling "does avoid the need to litigate the patent's validity (and also, any question of infringement)."[5] However, the Court dismissed this concern, noting that it would not be necessary to litigate the patent to answer the antitrust question because

> [a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market . . . .[6]

The Value of Ancillary Agreements

The primary focus of the economic analysis resulting from *Actavis* is on the nature and value of the ancillary agreements. The decision concludes that "the likelihood of a reverse payment bringing about anticompetitive effects depends on 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 justifications."[7] The Court further noted that "[w]here 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."[8]

In many instances, challenged reverse-payment settlements are complex transactions with ancillary agreements calling for cash and other considerations of various types flowing among parties. Several types of ancillary agreements have been used by settling parties in reverse-payment cases, such as:

- Licenses extended by the generic to the branded producer to make or sell products that are controlled by the generic;
- Supplemental or back-up supply agreements calling for the generic producer to provide production capacity for the branded producer;
- Joint marketing agreements calling for the generic to market the branded product as part of its product line, generally aimed at underserved medical provider populations;
- Joint development agreements in which the generic is paid to develop a new product; and
- Agreement by the branded producer not to issue authorized generic versions of the product for a certain period during the 180-day period of exclusivity that the generic might enjoy under the Hatch-Waxman Act.

When challenged, settling parties typically point to value provided by the generic to the branded producer under the terms of the ancillary agreements and attempt to show that consideration provided to the generic is explained by products or services provided, independent of the benefits and costs of the underlying patent settlement. Conversely, the FTC and private antitrust plaintiffs have consistently maintained that claimed justifications for such payments were pretextual. They have downplayed evidence showing the value of products or services to be provided by generics to branded producers in ancillary agreements.

It remains to be seen where lower courts will place the burden of the economic proof to demonstrate whether a large and unexplained reverse payment is present. In virtually every reverse settlement case, the agreements call for a large payment to the generic. In *K-Dur*, for example, the patentee paid $60 million to one of the generics. In *Actavis*, the patentee agreed to payments to several generics that might have amounted to hundreds of millions of dollars. Thus, future courts will most likely focus on the justification for payments rather than their absolute size. Following *Actavis*, trial courts will need to determine whether to require antitrust plaintiffs to evaluate these agreements and prove that the services offered by the generics in return do not justify the amounts paid, or allow plaintiffs to move forward based on assertions about lack of justification and require settling parties to prove that the value is justified.

After *Actavis*, to mount a challenge, plaintiffs may need to show that the claimed justifications for payments to the generic are invalid. The parties involved in a challenged transaction likely will engage in an analysis to determine the value of any consideration provided to the generic, in cash or other forms, by the branded manufacturer and to establish the value of any items provided by the generic settler in return to the patentee under the agreement that are independent of the timing of the generic's entry. If the value provided by the generic in the ancillary agreements equals or exceeds the pay-

ment from the branded manufacturer to the generic, then it would be difficult to find the presence of a reverse payment to the generic that was unexplained or otherwise suspect.

In most cases, payments to generics will be large and very clearly identified. Agreements usually call for specified cash payments. However, generally, the value of the items provided by the generic to the branded settler is less obvious. For example, it is difficult to assign a value to the right to sell a pharmaceutical product that is under development and thus has not yet received regulatory approval. Similarly, the potential success of a marketing initiative to introduce a drug product to a new group of doctors and health care providers may be challenging to evaluate in advance. In such instances, the valuation of ancillary agreements calls for a careful review of the facts and the terms of the agreements, along with reliable quantitative analysis and evaluation.

Evidence of contemporaneous analysis of the terms of the agreements may be significant for the outcome of a challenge. The settling parties may have evaluated some agreements in detail in a contemporaneous review. Evaluating the reasonableness of the methods and assumptions used in these reviews can be important. In our experience, by the time settlement discussions begin, parties often have not conducted careful and complete evaluations of all the terms of the ancillary agreements. Not surprisingly, during heated settlement negotiations, pressure to complete deals sometimes causes parties to enter arrangements without the careful analysis that would be normal in negotiations outside of litigation. The lack of contemporaneous documentation can be a hindrance when a challenge to the deal is encountered.

Ex post valuations of ancillary agreements, too, may be informative and in many cases, necessary. When evaluating the agreement later, experts may have access to relevant facts that were not available to the parties at the time of the agreement (such as information regarding comparable deals that can be used as a benchmark or because of knowledge of subsequent events, for example). However, the most relevant information likely would remain that which the parties had available at the time of the transaction.

The value of ancillary agreements included in reverse-payment settlements is likely to be tied to the success or failure of particular pharmaceutical products. These successes or failures depend upon clinical studies, regulatory approval, commercial acceptance, the existence and performance of competitive products, and many other factors. Developments related to one or two factors can significantly change the value over time of an ancillary agreement related to any given pharmaceutical product. Therefore, the appropriate valuation of an ancillary agreement for purposes of the antitrust issues addressed in *Actavis* depends critically upon understanding the market and regulatory circumstances related to the relevant product at the time the agreement was under negotiation. Subsequent events generally will be relevant only to the extent they reveal information that might have been known at the time of the agreement itself.[9]

We discuss below valuation issues that may occur with some types of ancillary agreements that have been included in reverse-payment settlements.

License Agreements. Branded manufacturers have sought and agreed to take licenses from the generic producers for products or technology unrelated to the products at issue in the underlying patent infringement case that led to the settlement. The FTC and antitrust plaintiffs have challenged the compensation paid for such licenses as being disguised payments for delay. If it can be established that the rights transferred to the patent owner have significant value, the license may help to provide the justification or explanation sought by the *Actavis* Court to assess the benefits of the reverse-payment transaction. However, demonstrating the value of licenses to developing products or technologies may be fraught with difficulty.

License agreements for products that are already on the market as well as for prospective products still in development are ubiquitous in the pharmaceuticals industry. Licenses are evaluated by prospective licensors and licensees and rights are transferred easily based on their perceived market value. Although the negotiation of and valuation of licenses is an everyday occurrence in the industry, demonstrating the validity of valuation estimates for a license in a litigation context can be problematic when adverse assumptions are made by plaintiffs challenging a deal.

Complexities in License Agreement Valuation: The *K-Dur* Example. Licenses from the generic to the branded producer were the primary elements of the ancillary agreements between the settling parties in the litigation that gave rise to the Third Circuit opinion in *K-Dur*.[10] The K-Dur settlement, and in particular the treatment of the licenses as a justification for the deal, illustrates the complexity that settling parties will have to deal with when using product licenses as elements of reverse-payment transactions after *Actavis*.

The Third Circuit summarized the long and tortuous history of litigation related to the K-Dur settlement in its 2012 ruling.[11] In the K-Dur settlement, the potential generic entrants provided licenses to the branded producer, Schering-Plough Corporation, to make or sell various branded and generic products controlled by the generics. The most significant of these licenses included a payment of $60 million by Schering to Upsher-Smith Laboratories, the first of the generics to seek entry, in exchange for the rights to several products.[12] The settling parties considered the majority of the value of the license agreement to be related to Niacor-SR, a product for which Upsher was in the process of gaining regulatory approval.

Schering and Upsher provided evidence to the FTC and the trial court that Niacor-SR had significant financial prospects, especially if added to Schering's portfolio of products in Europe. While settlement talks were being held, the product was evaluated by Schering business executives who had no knowledge of the status of the underlying litigation but were knowledgeable about the product market. They

determined that the expected value of the product far exceeded the cost of the license. These findings were presented to the Schering board and led to the approval of the settlement agreements. The FTC's Administrative Law Judge (ALJ) concluded that the antitrust challenger failed to demonstrate that the value of the licensed products was not at least $60 million.[13] As described by the Third Circuit, "The ALJ found that there was no reverse payment in the Schering-Upsher agreement because the licensing deal included in that agreement was separately valued and was not a payment to Upsher to delay generic entry."[14]

The full Commission reversed the ALJ and found that the settling parties could not show "that the payment was for something other than delay of generic entry . . . ."[15] Finally, the Eleventh Circuit ruled in 2006 in favor of the settling parties. The court "rejected the FTC's conclusion that Schering's $60 million payment to Upsher was for something other than the licenses it obtained, finding 'overwhelming evidence' that the payment was only for the licenses."[16]

How license agreements can be used in settlement agreements may depend on how the courts interpret the ruling in *Actavis*. In particular, as noted above, it is not clear which party will have the burden of proving the value of the ancillary agreement. The ALJ in 2002 essentially applied a rule-of-reason analysis, similar to that directed by *Actavis*, in evaluating the evidence on the license agreements and their value. The ALJ found the settling parties' evidence to be compelling and concluded that the plaintiff had not proven that any significant portion of the license payments constituted pay for delay.

The full Commission appears to have held the settling parties to a higher standard, seeking from them adequate proof that the payment was not for delay in order to avoid a prima facie case that the agreement was anticompetitive.[17] The Eleventh Circuit's rule-of-reason approach assumed that the burden of proving the bona fides of the payment rested on the settling parties and that they had met their burden. That court found that the antitrust plaintiff failed to meet its burden to counter the settling parties' evidence, stating "[t]here is nothing to refute that these payments are a fair price for Niacor and the other Upsher products."[18]

The Third Circuit's ruling in *K-Dur* seemed to go beyond what was subsequently decided in *Actavis*, saying that "a reverse payment is *prima facie* evidence of an unreasonable restraint of trade."[19] The court allowed that "a patent holder may attempt to rebut plaintiff's *prima facie* case of an unreasonable restraint of trade by arguing that there is no reverse payment because any money that changed hands was for something other than a delay in market entry."[20]

In the litigation involving the *K-Dur* settlement, even with a wealth of contemporaneous evidence and seemingly uncontested valuations performed independently at the time of the settlement negotiations, the settling parties have defended themselves against antitrust challenges for more than a decade. To some extent, the failure to reach an outcome in this matter is due in part to the uncertainties inherent in any analysis attempting to assess the future value of a pharmaceutical product, especially one that is not commercialized.

License Agreement Valuations, Given Hindsight. The *K-Dur* case also illustrates another problem that settling parties have in defending contemporaneous valuations of product licenses. Frequently, even the best contemporaneous evaluations turn out to be wrong given subsequent events. Hindsight can make it harder for settling parties to demonstrate the value of agreements.

At the time of the *K-Dur* settlement, which included a license for Upsher's Niacor-SR, evidence showed that Niacor-SR was well on its way to commercialization.[21] The target market for the product was thought to be expanding, as was illustrated by the successful launch of a similar niacin product by a rising competitor, Kos. In fact, Schering had unsuccessfully sought to acquire the Kos product to add it to its drug portfolio in this treatment area. These facts were apparently known to and considered by Schering executives in valuing the Niacor-SR product at the time of the Schering-Upsher agreement.

However, shortly after the agreement was completed, Upsher began to experience problems with the FDA in obtaining regulatory approval for Niacor-SR. At a minimum, moving forward would have entailed a significant delay and increased expenditures to pass to the next stage in the regulatory process. Around the same time, Kos began missing sales targets for its own niacin product leading to uncertainty about the size of the market and the potential pay-off for the development of Niacor-SR. As a result, Upsher discontinued development of the product.

The antitrust challengers seized on this failure to develop Niacor-SR as evidence that the payment to Upsher could not have represented value for the license, and the FTC cited this in its decision as a basis for overturning the trial court's ruling in favor of the settling parties.[22] The Eleventh Circuit discredited this use of hindsight. "The Commission's finding that the 'Upsher licenses were worth nothing to Schering' overlooks the very nature of the pharmaceutical industry where licenses are very often granted on drugs that never see the market."[23]

Antitrust plaintiffs might claim, as in the *K-Dur* matter, that the subpar performance of the benchmark product demonstrates the lack of value of the license agreement included in the reverse-payment settlement. However, these claims may be irrelevant unless it can also be demonstrated that the subsequent problems contributing to the product's shortfall were known or foreseeable and not captured in the original valuation model. This evaluation may come down to an assessment of the assumptions of the model given what was known (and what could have been known) at the time of the agreement, and not in light of subsequent events that were not foreseeable at the time the agreement was negotiated.

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assumptions used in any analysis of value. Also, the experience of a similar product could represent a reasonable benchmark for anticipated sales to test the assumptions of a valuation model. Settling parties might conduct or commission studies to evaluate the potential market and value for licensed products. When conducting such studies, the licensee can document underlying assumptions. Finally, the licensee can continue to monitor the progress of the licensed products and document changes in market conditions as well as in the rationale for any changes in plans with regard to these products.

Back-up or Supplemental Manufacturing Capacity. Reverse-payment settlements may include an ancillary agreement in which the generic party agrees to provide back-up or supplemental manufacturing capacity for the branded manufacturer. The provision of additional manufacturing capacity can serve as supply insurance and be of significant value to a branded manufacturer. For example, the agreement that led Actavis to settle the patent litigation involving its AndroGel product included significant payments by the branded manufacturer to a potential generic entrant for provision of backup manufacturing capacity.

Disruptions in supply can cause expensive problems for producers and for patients using a branded product. Producers typically develop plans in case of disruption, especially as a pharmaceutical product gains market acceptance. In some cases, the producer builds and maintains capacity in-house. In other cases, the producer relies on back-up capacity obtained from a third party. Second-sourcing can greatly reduce a manufacturer's risk.

In many cases, a potential generic entrant represents a viable and efficient source for back-up manufacturing capacity. In some cases, the generic may have been developing capacity to prepare for the possibility of entry. The generic might already be selling related products that use some or all of the active ingredients and have experience handling, sometimes sensitive, ingredients in a manner acceptable to regulators.

Valuing such an agreement is analogous to the consideration of risk, cost, and value of an insurance contract. A straightforward quantitative method that is regularly used for making business decisions can be appropriate for estimating the value of the back-up manufacturing. This method incorporates the likelihood of a failure in the patentee's supply (e.g., probability of an interruption), estimates of the extent of possible failures (e.g., the potential length of disruption and percent of supply disrupted), and estimates of short-term and potential long-term losses from disruption. Avoiding the potential costs of disruption can be compared with the cost of obtaining back up capacity, particularly in the case of growing markets where expansion is anticipated and the development of capacity is expensive and lengthy.

However, as with the valuation of future product licenses, standard business analysis of these agreements may be difficult to present in the context of litigation because using this model involves adoption of assumptions about future events that can be difficult to assess. The value of a back-up manufacturing agreement may be sensitive to the facts related to a particular pharmaceutical product as well as the assumptions related to the likelihood and extent of disruption. For example, working with some chemical agents can be challenging and potentially even dangerous. In such instances, the number of facilities equipped to work with particular chemicals can be relatively small. As a result, back-up manufacturing may be more costly for the branded manufacturer (because it has fewer options) and also more valuable (because the probability of requiring back-up manufacturing is greater).

Note that the value of a back-up manufacturing plan will also depend upon the profitability of the branded product and the anticipated continued profitability of the product during the life of the back-up manufacturing agreement. An agreement for ten years where generics are expected to enter at year seven would have less value to the branded manufacturer than an agreement in which no generics were anticipated for the full ten-year term of an agreement.

Contemporaneous information about the anticipated likelihood of the use of back-up capacity as well as alternatives available at the time provides for a more robust analysis. To the extent that the manufacturer has received other quotes for the provision of back-up or supplemental capacity, these are informative. There can be a divergence between the value that a branded manufacturer receives from instituting a back-up manufacturing plan and the amount that a branded manufacturer might be expected to pay for a specific back-up manufacturing plan. A branded manufacturer might receive extraordinary value from having back-up manufacturing since even a small risk of lost sales (and corresponding profits) for a period can be very costly. However, if numerous viable suppliers are able to provide back-up capacity, then the amount that the branded manufacturer would normally pay for back-up manufacturing would be smaller than if sources were limited.

Joint Marketing Agreements. Another feature of the AndroGel settlement, and of other settlements we are familiar with, relates to an agreement by a generic to provide marketing services to the branded manufacturer in exchange for up-front and/or profit sharing payments. Opportunities may exist to reach procompetitive agreements that expand distribution of a patented product.

Branded manufacturers may have distribution and marketing capabilities and strengths focused on a limited number of treatment or specialty areas. Based on its historical product mix and the development of its sales operation, a company might have an advantage in selling to a particular type of physician or other provider. At the same time, that company may have little coverage of alternative markets in which their products might be successful if supported by a marketing effort. If a generic possesses or is well-positioned to develop marketing and distribution capability in areas where the branded manufacturer is relatively weak, a joint marketing agreement can provide substantial value. By entering into a joint marketing agreement, the branded manufacturer may be able to increase its sales efficiently and quickly. For example, in the case of AndroGel, in exchange for specified payments, one of the generic parties agreed to market the product to urologists and another generic agreed to market to primary care physicians.[24]

The value of this type of arrangement to the branded manufacturer is driven by the anticipated profits from the marketing and distribution services provided by the generic party compared with the absence of the agreement. If the branded manufacturer can anticipate additional sales from the joint marketing agreement over and above what would otherwise be achieved, then the value of the agreement could be significant even after payment to the generic for the service. Such a joint marketing agreement can also result in benefits accruing directly to consumers. For example, the drug may be distributed more widely as a result of the agreement than would otherwise happen.

Once again, there may be disparities between the contemporaneous valuation of the marketing agreement and the results later derived from that agreement. Parties seeking to use such agreements in settlements would be advised to create clear assessments of the expectations for the marketing programs and to document subsequent performance, including any changes in the market or the parties' operations that might have a bearing on the results generated as part of the agreements.

Joint Development Agreements. Another feature we have seen in connection with settlements (although we have not seen any such agreements referred to in litigated cases) involves an agreement between a branded and generic producer to develop a new pharmaceutical product that might be either branded or generic. Under such an agreement, the patentee elicits a commitment from the generic party to develop and test a version of a product. The branded manufacturer pays the generic to develop the new product, and the branded manufacturer and generic might jointly market the product or each might introduce versions of the new product. The economic analysis that would be required for this type of transaction is very similar to that described in connection with product licenses. In fact, the Schering-Upsher license noted above with regard to Niacor-SR might be characterized as a joint development agreement.

Agreements such as this are a reminder that in the pharmaceutical industry vertical relationships in product development, marketing, and distribution can generate procompetitive efficiencies, even among those who might be horizontal competitors in other areas. In using such an agreement as part of a settlement transaction, the parties may face allegations of reverse payment. However, to the extent that the dollar flows from the branded manufacturer to the generic party are related to development costs, they would appear justifiable under *Actavis*.

As with other types of transactions described, joint development agreements may be difficult to value because of the uncertainty related to such factors as clinical studies, regulatory approval, the efficacy of the product, the development of competitive products, and general market acceptance. Contemporaneous documents and valuations can be informative for joint development agreements. Ex post valuations can provide valuable insight assuming that information about the likelihood for success and the potential size of the market for the product under development is available, perhaps even estimated with information from similar products. However, demonstrating the value of these agreements in court might be difficult.

No Authorized Generics. In recent years, a number of settlements have included an agreement by the branded manufacturer not to introduce an authorized generic (AG) product that would compete with the potential generic entrant during the 180-day period of exclusivity the generic might otherwise enjoy under the Hatch-Waxman Act. For example, Wyeth apparently reached such an agreement in settling litigation over its Effexor XR product. That agreement has been challenged by a number of private antitrust plaintiffs, and the FTC has argued that the approach set forth in *Actavis* applies.[25] Such agreements are not ancillary agreements in the same sense as the others we describe. Instead, this type of agreement, on its own, merely substitutes one form of consideration paid to the generic for another, rather than being a free-standing transaction with a two-way flow of value.

Frequently, when a generic enters the market, the branded manufacturer continues selling its branded product but also introduces an AG. The vast majority of consumers purchase one of the two generics (either from the generic or from the branded manufacturer) that have been introduced during the 180-day exclusivity period. The branded product also continues to be sold to a small minority of consumers, often at a higher price than before the generics were introduced. The presence of the AG substantially reduces the profits the generic party might have expected in the absence of the AG and protects a portion of the branded producer's profits that might otherwise be lost.

When a branded producer provides compensation in the form of an agreement not to introduce an AG, the potential anticompetitive effect of the settlement may be larger than in a similar deal in which compensation is paid in cash. This is

because when a branded producer pays cash it bears the entire burden of the payment. However, by refraining from introducing an AG, the firm pushes some of the costs of a deal onto consumers by decreasing competition during the 180-day exclusivity period.

For example, a branded producer might agree to a $20 million royalty payment in an ancillary agreement with a potential generic entrant. However, the parties may recognize that the generic could expect $20 million or more in additional profits during its 180-day exclusivity period if an AG was not introduced. If the branded producer agrees to compensate the generic by not introducing an AG, then this commitment could provide great value to the generic and represent a lower cost for the branded manufacturer. In this example, part of the $20 million expected by the generic would derive from an ability to charge higher prices during the 180-day period for the product than would have been possible in the face of competition from an AG.

With the agreement not to introduce the AG, consumers would not enjoy the benefits of the additional generic competition and the settling parties might be able to extract more from the deal as a result. However, the settling parties would presumably have the ability under *Actavis* to show that in the context of the entire settlement, including any other ancillary agreements, the transaction is still justified.

Implications for Future Settlements and Litigation

Parties involved in challenges to reverse-payment agreements will need to evaluate the implications of *Actavis* and how the lower courts fashion acceptable methods of proof and analysis consistent with the Court's opinion to sustain a rule-of-reason approach. The direction of future litigation challenging reverse-payment settlements likely will turn on how the courts analyze and assign the burden of proof for showing the value of ancillary agreements. Trial courts will be required to rule on the acceptability of the evidence presented by each side to demonstrate the value or lack thereof conveyed by the ancillary agreements.

Actavis may lead to the continued challenge of almost every reverse-payment settlement. Under *Actavis*, given the necessarily subjective and uncertain estimates that must be made to establish valuations for typical ancillary agreements, challengers may be able to cast sufficient doubt on the valuations to mount a challenge, and settling parties may find it unwise to continue to use reverse-payment settlements when factoring in the costs of defending the extensive litigation. ■

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[1] FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013).

[2] The Eleventh Circuit found the settlement in *Actavis* immune from antitrust challenge, reasoning that the settlement had not attempted to expand the rights granted the branded manufacturer under patent law. FTC v. Watson Pharms., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012). *See also* Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1304 (11th Cir. 2003). The Federal Circuit and the Second Circuit ruled similarly in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323, 1332–37 (Fed. Cir. 2008), and *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187, 213 (2d Cir. 2012).

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

[4] *See, e.g.*, *Watson Pharmaceuticals*, 677 F.3d at 1305 (noting the FTC argument that an agreement's reverse-payment settlement was designed to delay entry in order to maintain monopoly profits at the expense of the consumer).

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

[6] *Id.*

[7] *Id.* at 2237.

[8] *Id.* at 2236.

[9] Subsequent information may also be relevant in addressing claims that a deal was pretextual in nature. For example, if an ancillary agreement required that the generic settler provide marketing support (such as hiring or training sales agents, etc.), that party's subsequent actions to provide that support might be relevant in assessing whether the agreement was pretextual.

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

[11] The agreement at issue was concluded in 1997. After a two-year investigation the FTC sued the parties in 2001. An FTC Administrative Law Judge (ALJ) ruled in favor of the settling parties after a trial in 2002. Schering-Plough Corp., FTC Docket No. 9297, 2002 WL 1488085 (June 27, 2002) (Initial Decision) [hereinafter *Schering-Plough* FTC Initial Decision]. The Commission reversed the ALJ in late 2003, and issued an order against the settling parties. Schering-Plough Corp., FTC Docket No. 9297, 2003 WL 25797209 (Dec. 8, 2003) (Final Order) [hereinafter *Schering-Plough* FTC Final Order]. On appeal, the Eleventh Circuit reversed the Commission ruling and upheld the settlement agreement. Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005) [hereinafter *Schering-Plough* 11th Circuit decision]. The Third Circuit's decision on the case in 2012 resulted from private antitrust actions brought following the original FTC litigation. *K-Dur*, 686 F.3d 197 (overturning the lower court ruling dismissing the antitrust complaint).

[12] The facts relating to the licenses included in the Schering-Upsher agreement are taken from the ALJ's decision unless otherwise noted. *Schering-Plough* FTC Initial Decision, *supra* note 11.

[13] *Id.* at *46.

[14] *K-Dur*, 686 F.3d at 207 (3d Cir. 2012). *See also Schering-Plough* FTC Initial Decision, *supra* note 11, at *92.

[15] *K-Dur*, 686 F.3d at 207; *see also Schering-Plough* FTC Final Order, *supra* note 11, at *967.

[16] *K-Dur*, 686 F.3d at 212; *see also Schering-Plough* 11th Circuit decision, 402 F.3d at 1070.

[17] *K-Dur*, 686 F.3d at 207; *see also Schering-Plough* FTC Final Order, *supra* note 11, at *1051–52.

[18] *Schering-Plough* 11th Circuit decision, 402 F.3d at 1071.

[19] *K-Dur*, 686 F.3d at 218.

[20] *Id.*

[21] The following facts are summarized from *Schering-Plough* FTC Initial Decision, *supra* note 11, at *30–54.

[22] *Schering-Plough* FTC Final Order, *supra* note 11, at *1051–52.

[23] *Schering-Plough* 11th Circuit decision, 402 F.3d at 1071.

[24] *Watson Pharmaceuticals*, 677 F.3d at 1305.

[25] Fed. Trade Comm'n Brief as *Amicus Curiae*, *In re* Effexor XR Antitrust Litig., Lead Case No. 3-11-cv-05479 (D.N.J. Aug. 14, 2013); *see also FTC Wants to Extend Actavis to Authorized Generics Deals*, LAW360 (Aug. 16, 2013).