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I. INTRODUCTION

In June 2013, the Supreme Court ruled in *FTC v. Actavis* that reverse-payment pharmaceutical patent settlement agreements are subject to rule of reason analysis under the antitrust laws. In doing so, the Court not only rejected both the FTC's position that such agreements should be presumptively unlawful and the position of pharmaceutical manufacturers that such agreements should only be subject to scrutiny where they exceed the scope of the relevant patent, but also left it to the lower courts to develop the details of the framework to be applied. While this outcome did not come as a surprise to many, by declining to adopt either of these arguably simpler approaches, the ruling likely raised as many questions as it answered.

In many ways, before the ink was even dry on the Supreme Court's ruling in *Actavis*, the next front in the pharmaceutical reverse-payment saga was already clear. Parties engaged in reverse-payment related litigation prior to the ruling had already renewed arguments regarding the issue in the wake of the Third Circuit's then-recent ruling in *K-Dur* that reverse-payment patent settlement agreements were presumptively unlawful under the antitrust laws.

With this break from the scope-of-the-patent test, pharmaceutical firms (branded and generic alike) were faced with the prospect of a narrower set of paths through which to fend off reverse-payment suits at early stages of litigation. At the same time, given the intense scrutiny afforded these agreements by the FTC and private plaintiffs over the previous decade, the agreements themselves had already evolved significantly—few involved the simple, otherwise unexplained transfer of large sums of money anymore. Instead, many agreements had begun to provide for a range of ongoing relationships between the settling parties—sometimes limited to the products at issue in the patent litigation and sometimes extending beyond. Given this confluence of factors, it is not all together surprising that the wake of the Supreme Court finally weighing in on the issue has brought the parties back around to the very question of what constitutes a reverse "payment."

Currently a number of courts are actively trying to carve the first contours of the rule of reason analysis called for under *Actavis* by attempting to determine whether scrutiny under *Actavis* is limited to cash payments from a brand to a generic or, if instead, the rule is broad enough to also reach other non-cash forms of consideration.

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II. THE RISE OF NON-CASH FORMS OF CONSIDERATION

As mentioned above, with intensified scrutiny of reverse-payment patent settlements over the past decade, the structure of these agreements has evolved. Instead of payments for the generic's commitment to refrain from entering the market, as early as 2005 the FTC reported that agreements notified to it under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") were including other types of provisions such as "side deals" between the brand and the generic.[2]

These side deals typically take one of the following forms: (1) IP licenses, (2) co-promotion agreements, (3) supply agreements, and/or (4) co-development agreements. It is important to note that each of these types of side-deals typically involve actual cash payments between the parties and, in some instances, where an agreement provides for a combination of different types of side-deals, payments may flow in both directions. However, other types of provisions that have also appeared with increasing frequency do not necessarily contemplate any payments being exchanged between the parties.

In particular, the FTC has reported that increasing numbers of agreements contain provisions whereby the brand commits not to market an authorized generic ("AG") during a first Abbreviated New Drug Application ("ANDA") filer's 180-day exclusivity period. These so-called "No-AG" agreements are typically structured in one of two ways—either as a simple commitment by a brand not to market an AG for a fixed period of time (nor license a third party to do so) or through the grant of an exclusive license to the generic for the AG product, which is exclusive even as to the patentee.

The FTC reports that 19 of the final settlements reported to the agency in FY 2012[3] and 24.8 percent of the total number of final agreements filed with the agency between FY 2004 and FY 2010 contained this type of provision.[4] Although this type of provision does not involve cash payments between the parties, these provisions may be valuable to a generic first-filer. The FTC has found that the presence of an AG reduces the revenues of the first-filer generic by an average

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[2] *Compare* FEDERAL TRADE COMMISSION, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2004, *available at* http://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/050107medicareactrpt.pdf, *with* FEDERAL TRADE COMMISSION, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2005, *available at* http://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/fy2005drugsettlementsrpt.pdf.

[3] FEDERAL TRADE COMMISSION, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Overview of Agreements Filed in FY 2012, *available at* http://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/130117mmareport.pdf.

[4] FEDERAL TRADE COMMISSION, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact, August 2011 at vi, *available at* http://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

of 40-52 percent during the exclusivity period.[5] Thus, by ensuring that the brand will not compete by means of an AG for some period of time, these "No-AG" provisions are said to protect generic revenues.

III. *FTC V. ACTAVIS*

In *Actavis*, the Court held that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effect," namely that reverse payments can be used by a patentee "to avoid the risk of patent invalidation or a finding of noninfringement."[6] The likelihood of a payment having such 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."[7]

Justice Breyer, writing for the majority, reasoned that such a rule is capable of being administered by a court in light of the fact that it will not normally be necessary "to litigate the patent's validity…." because "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival."[8] The Court specifically identified two potential justifications for reverse payments—(1) where the payment "amount[s] to no more than a rough approximation of the litigation expenses saved through the settlement" and (2) where a payment "reflect[s] compensation for other services that the generic has promised to perform"—but also left open the possibility that there may be other justifications.

With these guideposts, the Court left it to lower courts to structure the precise rule of reason framework to be applied in this context in such a way as will "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…"[9]

Thus, in the view of the majority, the size and character of the alleged "payment" is central to each of the key aspects of the ruling—it is the metric by which the anticompetitive potential of this type of settlement agreement, as well as the adequacy of asserted justifications, are to be assessed, and is also the "workable surrogate for a patent's weakness" which avoids the need to delve into the merits of the underlying patent litigation, thereby making these cases administrable in practice.[10]

Indeed, the majority states that the size of the payment is "itself a strong indicator of power" to charge higher prices because a patentee making such a payment would likely have the power to bring about the anticompetitive harm of concern in the context of reverse payments. Moreover, the payment may be indicative of intent because it "may…provide strong evidence

[5] *Id.* at 33 (finding that during the exclusivity period "wholesale expenditures on the first-filer's generic drug—a proxy for revenues—were 40 to 52 percent lower, when an AG was present.").

[6] *Federal Trade Commission v. Actavis, Inc.*, 133 S.Ct. 2223, 2236-37 (June 17, 2013).

[7] *Id.* at 2237.

[8] *Id.* at 2244.

[9] *Id.* at 2238.

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

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."[11]

Despite this emphasis on the presence and relative size of a "payment" as critical elements of the Court's core holdings in *Actavis*, the question of what actually constitutes a "payment" in this context appears to be among the questions left to lower courts to determine. The opinion does not directly address the issue. In the few instances where the majority uses something beyond a generic reference to "payment[s]," the Court appears to be referencing monetary forms of payment. For example, in describing the nature of reverse payments, the Court states that "[i]n reverse payment settlements…a party with no claim for damages…walks away with ***money*** simply so it will stay away from the patentee's market."[12] (emphasis added). However this might also be explained by the fact that the only forms of payment alleged in *Actavis* involved actual monetary transfers from the brand to the generic—payments in return for the generic firms promoting the branded drug at issue in the patent litigation to prescribers.[13]

Unfortunately the dissent in *Actavis* also did not provide any further clarity on this point. In a single paragraph, the dissent implies that it understood the majority to only be addressing cash payments while at the same time stating that the majority's logic cannot reasonably be limited to just cash payments. Indeed, writing on behalf of the three dissenting justices, Chief Justice Roberts asserted that:

> [the majority's] logic—that taking away any chance that a patent will be invalidated is itself an antitrust problem—cannot possibly be limited to reverse-payment agreements, or those that are 'large. The Government's brief acknowledges as much, suggesting that if antitrust scrutiny is invited for such cash payments, it may also be required for 'other consideration' and 'alternative arrangements.'[14] (internal citations omitted)

These are the muddied waters that federal district courts and parties in three ongoing private reverse payment suits have recently tried to clarify.

IV. RECENT CASES: *In re Lamictal*, *In re Lipitor*, and *In re Nexium*

So far only three courts have addressed this aspect of *Actavis* to any degree—two U.S. District Courts in the District of New Jersey and one in the District of Massachusetts—only one of which actually decided the issue directly. Careful consideration of the approach taken in each of these cases is particularly useful because even these initial indications already reflect a split among lower courts.

[11] *Id.* at 2235.

[12] *Id.* at 2243; *see also Id.* ("But the dissent appears also to suggest that reverse payment settlements—e.g., in which A, the plaintiff, pays ***money*** to defendant B purely so B will give up the patent fight…") (emphasis added)

[13] *Id.* at 2229.

[14] *Id.* at 2246 (Roberts, J., dissenting)

A. In re Lamictal

In *Lamictal*, the only case so far in which the issue of non-cash payments was actually decided and the most recent word on the issue, Judge William H. Walls held that only payments involving monetary transfers are subject to antitrust scrutiny under *Actavis*.[15] The agreements at issue settled patent litigation between GlaxoSmithKline ("GSK") and Teva Pharmaceuticals ("Teva") related to GSK's epilepsy and bipolar disorder product, Lamictal, which is available in both tablet and chewable forms. Under the terms of the agreement, Teva was permitted to sell generic chewables approximately 37 months prior to patent expiration and generic tablets approximately six months prior to patent expiration. GSK also granted Teva an exclusive license to the relevant Lamictal patents, which was exclusive even as to GSK during Teva's 180-day first-filer exclusivity period.

According to Judge Walls, the first step under the *Actavis* framework is to determine whether an agreement involves a reverse payment and this, in turn, "hinges on what the parties exchanged in the settlement and must include money."[16] Though he did not find that *Actavis* decided the matter expressly, Judge Walls relied heavily upon the fact that in his view "[b]oth the majority and dissenting opinions reek with discussion of [the] payment of money."[17] In particular, he highlighted the dissent in *Actavis* (discussed above) which he characterized as having critiqued "the majority precisely because it drew a line between monetary and non-monetary payments."[18]

More broadly though, Judge Walls concluded that the reasonableness of the settlement agreement further bolstered his conclusion that the agreement was not of the sort that is subject to *Actavis* scrutiny. In this regard, he specifically noted three features of the agreement which in his view counseled against the need for scrutiny in that context: (1) Teva was allowed to enter the market prior to patent expiry, (2) there was no monetary payment from the brand to the generic, and (3) the exclusive license was for a relatively brief period.[19]

B. In re Lipitor

In *Lipitor*, a different federal district court in New Jersey granted plaintiffs leave to amend their complaint following *Actavis* to include allegations of non-monetary forms of payment.[20] The agreements at issue in the case provided for Pfizer's forgiveness of outstanding monetary judgments against Ranbaxy and the grant of a right to market generic Lipitor in at least eleven international markets.[21] In allowing the amendments, Judge Peter G. Sheridan declined to directly decide the substantive question, but did observe that "nothing in *Actavis* strictly requires that the payment be in the form of money…"[22]

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[15] *In re Lamictal Direct Purchaser Antitrust Litigation*, No. 12-995, 2014 WL 282755 (D.N.J. Jan. 24, 2014).
[16] *Id.* at *5.
[17] *Id.* at *7.
[18] *Id.* at *8.
[19] *Id.* at *9.
[20] *In re Lipitor Antitrust Litigation*, No. 12-2389, 2013 WL 4780496 (D.N.J. Sept. 5, 2013).
[21] *Id.* at *11.
[22] *Id.* at *26.

C. In re Nexium

Judge William G. Young made a similar observation in *Nexium*, a case currently pending in federal district court in Massachusetts, in granting the plaintiffs leave to amend their complaint in light of *Actavis* to include allegations of non-cash payments. The allegations asserted in *Nexium* center around agreements between AstraZeneca and three generic manufacturers—Ranbaxy, Teva, and Dr. Reddy's. Under these agreements, Ranbaxy received an exclusive license and cash payments in return for Ranbaxy's provision of manufacturing and distribution services to AstraZeneca. With respect to Teva and Dr. Reddy's, AstraZeneca forgave significant portions of contingent liabilities faced by the firms.

While conceding that the Court "spoke only to the merits of cash payouts," Judge Young emphasized that "[n]owhere in *Actavis* did the Supreme Court explicitly require some sort of monetary transaction to take place for an agreement between a brand and generic manufacturer to constitute a reverse payment."[23] Judge Young further reasoned that "a broader interpretation of the word 'payment'" would "serve[] the purpose of aligning the law with modern-day realities."[24]

V. ANALYSIS

As reflected in the split summarized above, the question of whether non-cash forms of consideration are also subject to scrutiny under *Actavis* in the context of pharmaceutical patent settlements is far from decided. However, in the meantime it is worthwhile to consider the potential implications if they are.

First, it will likely result in a far broader range of agreements being subjected to intense scrutiny. It is common ground that value can be transferred between parties to a settlement agreement without the exchange of actual money. Indeed, as Judge Posner observed in an earlier reverse-payment case, "any settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement."[25] Beyond just agreements involving No-AG provisions, such a rule could also potentially reach agreements where the brand grants the generic a non-exclusive license or agrees to act as a backup supplier of the product in the event of a shortage. Both of these are examples of provisions that likely convey some value to the generic without a cash payment, but can also play a key role in facilitating earlier generic entry when used in connection with a negotiated entry date.

As has been recently observed by industry representatives, this broad interpretation could also potentially sweep in other types of agreements that are widely viewed as pro-competitive, such as shared patented Risk Evaluation and Mitigation Strategies ("REMS") programs. To the extent the licensing of a shared REMS program is viewed as potentially constituting a non-cash form of payment, this could discourage branded firms from granting such licenses which could, in turn, have the effect of slowing generic entry and imposing additional costs on generics.

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[23] *In re Nexium (Esomeprazole) Antitrust Litigation*, No. 12-02409, 2013 WL 4832176, *15 (D. Mass. Sept. 11, 2013).

[24] *Id.*

[25] *Asahi Glass Co., Ltd. v. Pentech Pharms., Inc.*, 289 F.Supp. 2d 986, 994 (N.D. Ill. 2003)

Second, such a rule may discourage the settlement of patent litigation by subjecting agreements which may in fact involve no actual payment (even under this expanded standard) to significant economic scrutiny. Whereas the existence and value of a cash payment is clear without further analysis, the value of a so-called No-AG clause or other forms of non-cash consideration in a given context is far less clear. Taking just the example of No-AG clauses, as the FTC itself has found, some branded manufacturers simply do not choose to authorize generic drugs under their NDAs even in the face of generic entry, and others do so only for a subset of their NDA-covered drugs.[26] If a branded firm in fact has no intention to introduce an AG for a particular product, a No-AG clause may still be *perceived* by a generic as having some value (at least as reassurance to the generic), but in reality essentially has none and is costless to the brand. More importantly, in these circumstances the brand and generic cannot be said to be allocating markets because the brand never had any intention to enter the generic market in the first place. In light of this, plaintiffs should bear a relatively significant burden in proving the existence and size of a payment on the basis of non-cash consideration alone.

Thus, as FTC Commissioner Joshua Wright recently observed, this broad interpretation of the scope of *Actavis* will likely prove to be a "boon" for economic litigation consulting firms. Significant economic analysis may be required to determine whether a brand was likely to otherwise market an AG in the circumstances and thus whether the No-AG clause had any value.

[26] FTC Authorized Generic Drugs, *supra* note 4 at 15-17.