Recent Court Cases Interpreting "Reverse Payments" Post-*Actavis*

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Patent settlement agreements were traditionally deemed outside the purview of antitrust scrutiny unless the patent holder's conduct fell outside the legitimate scope of the patent's exclusionary power. This all changed when the Supreme Court rejected the scope of the patent test in *FTC v. Actavis*, and determined that reverse payment settlements, in which a branded pharmaceutical company paid a generic drug company to delay entry into the market, could violate the Sherman Act. Since *Actavis*, the lower courts have grappled with what constitutes an illicit reverse payment, with the analysis turning on whether there was any other value given to the generic drug company beyond an agreement that the generic drug company can enter the market prior to the branded pharmaceutical company's patent expiring, and whether that value was justified by pro-competitive benefits.

Hatch-Waxman Act Sets Stage for Reverse Payment Settlements to Flourish

The Hatch-Waxman Act provides a way for generic drug companies to launch drugs by "ensuring that weak patents do not delay lower-cost generic competition." Generic companies can file an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration, showing that the generic drug is equivalent to the branded drug and that any patent covering the branded drug is non-infringed, invalid or unenforceable. Once the generic drug company files its patent certification that Orange Book listed patents are not infringed, invalid or unenforceable, a branded pharmaceutical company can sue the generic drug company for patent infringement and the generic drug company is forced to defend. If the branded company is not successful in its litigation against the ANDA filers, it will likely face generic competition prior to patent expiration. Given the risks of litigation and the potential economic ramifications, branded companies seek to settle patent infringement actions with the generic companies. These settlements have sometimes included a payment by the branded pharmaceutical company to the generic drug company in exchange for resolving the litigation and an agreement that the generic drug company would not enter the market until some specified date in the future, and are referred to as "pay for delay" or "reverse payments."

Actavis Exposed Reverse Payment Settlements to Antitrust Scrutiny

The Supreme Court in *FTC v. Actavis*, 133 S. Ct. 2223 (2013), addressed a split of authority among the circuit courts on whether reverse payments were immune from antitrust review or presumptively unlawful. The Supreme Court rejected the scope of the patent test that most circuit courts had followed, explaining that patent settlements, especially in the context of Hatch-Waxman litigation, must be subject to analysis under the rule of reason whereby the court will assess the procompetive and anticompetitive effects of the settlement. This will include an assessment of the industry and, potentially, the validity of the patent as well as potential justifications for the payment (e.g. its size, relation to future litigation costs and its independence from other services for which the payment may be justified.) Thus, a large and unjustified reverse payment, such as cash going from the patentee to the infringer or above market rates for promotional services in exchange for an agreement to not launch a generic product prior to patent expiration, can bring "significant anticompetitive effects" and may be deemed unlawful. A more detailed analysis of the *Actavis* decision can be found here.

Questions Remain on Reverse Payment Definition Under *Actavis*

Since *Actavis*, circuit courts have taken an expansive approach to identifying reverse payments, while lower courts have taken a more narrow approach. But, the circuit and district courts have agreed that plaintiffs must allege facts sufficient to show that the amount or value of the reverse payment was unjustified to survive a motion to dismiss. The following four cases demonstrate how these courts have grappled with *Actavis*.

King Drug Co. v. SmithKline Beecham Corp.

The U.S. Court of Appeals for the Third Circuit in *King Drug Co. v. SmithKline Beecham Corp.* [1] held that reverse payments are not limited to cash but include other forms of consideration and vacated the motion to dismiss. There, SmithKline (now GSK) sued Teva Pharmaceuticals USA, Inc. after Teva filed an ANDA to make a generic version of Lamictal in 2002. The parties settled, allowing Teva to almost immediately launch a chewable version of Lamictal, which

is a far less lucrative version of Lamictal than the tablet version. Teva agreed not to launch a generic tablet until the day before the patent expired in 2008. In exchange, GSK agreed not to launch an "authorized" generic drug during Teva's 180-day exclusivity period.[ ] A class of Lamictal purchasers sued GSK and Teva for violating the antitrust laws, and the district court dismissed the complaint, in part, because there was no actual payment of money. The Third Circuit reversed, finding that GSK's agreement not to launch an authorized generic drug during Teva's exclusivity period was "an unexplained large transfer of value from the patent holder to the alleged infringer." Thus, these types of "no-AG agreements are likely to present the same types of problems as reverse payments of cash" because the agreements "may be of great monetary value to Teva as the first-filing generic" and allow GSK to leverage its patent to eliminate the risk of competition.

In re: Loestrin 24 Fe Antitrust Litigation

Similarly, the U.S. Court of Appeals for the First Circuit held that non-cash payments to accused infringers, such as "above-market" promotional deals, can violate antitrust laws. Warner Chilcott manufactured Loestrin 24 Fe, an oral contraceptive, and sued two generic companies for patent infringements after they filed an ANDA. Warner Chilcott settled the suits, agreeing not to market an authorized generic drug during the 180-day exclusivity period and paying the generic companies' fees to market an unrelated Warner drug. A class of direct purchasers sued Warner Chilcott, as well as Watson and Lupin for violating Section 1 of the Sherman Act, and the district court dismissed, holding *Actavis* was limited to cash payments. The First Circuit reversed, holding that "payments" include more than cash consideration, such as paying for marketing services above market rates. That is, reverse payments include indirect compensation as well. The First Circuit also explained that "plaintiffs must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under *Actavis*."

FTC v. AbbVie Inc.

Conversely, the District Court for the Eastern District of Pennsylvania granted a motion to dismiss the FTC's antitrust action against AbbVie and Teva because the settlement agreement between the parties did not contain a payment to delay competition, and the agreement had procomopetitive effects by allowing increased market entry. AbbVie and Teva settled an infringement suit after Teva filed an ANDA. The settlement allowed Teva to market a generic version of AndroGel years before the patent expired. In addition, AbbVie gave Teva a license to manufacture a generic form of TriCor. The FTC challenged the agreement, alleging that the TriCor agreement was a payment to Teva. The district court dismissed the complaint because the two agreements were not anticompetitive. The AndroGel agreement allowed Teva to enter the market "almost six years prior" to the expiration of AbbVie's patent, and AbbVie would supply TriCor to Teva for the cost of production and a royalty under the TriCor agreement.

In re: Actos End Payor Antitrust Litigation

In another case, *In re Actos End Payor Antitrust Litigation* , Takeda sued several generic manufacturers for infringing patents covering diabetes drugs before settling. Under the terms of the settlement, the generic companies dropped their challenges to Takeda's patents. In return, Takeda granted a non-exclusive license agreement that allowed the generic manufacturers to market generic versions of Actos years before the patents expired. Each settlement agreement contained an acceleration clause that allowed the generic drug manufacturers to launch generic versions of Actos if another generic drug company launched earlier. A class of indirect purchasers sued Takeda and generic drug manufacturers for violating Section 1 of the Sherman Act, alleging that the acceleration clauses in the settlement agreements induced the generic companies to drop their challenges to Takeda's patents. The plaintiffs claimed that the acceleration clauses also deterred other generic drug companies from entering the market. In dismissing the plaintiffs' complaint, the U.S. District Court for the Southern District of New York reasoned that the settlement agreement did not contain any payments to preserve Takeda's monopoly power because the agreements granted the generic drug companies a license to the patents. Further, the court also held that, even if the settlement agreements contained reverse payments, the complaint did not sufficiently allege that the payments were either large or unjustified.

Conclusion

To date, courts have interpreted *Actavis* and improper reverse payments to extend beyond cash payments from a branded pharmaceutical company to a generic drug company. The question remains as to how far that analysis will extend. Thus far indirect forms of payments, such as not launching an authorized generic drug or paying above market rates for promotional work, have been found to be unjustified reverse payments. But at the core of the analysis is a determination of the value of the settlement to the generic drug company and whether that value is commensurate with pro-competitive benefits (e.g., early market entry, patent licenses, resolution of litigation) or is an unjustified payment to secure the branded pharmaceutical company's monopoly.

Accordingly, pharmaceutical companies should focus any patent litigation settlement agreements on the entry date of the generic drug company or market rate for services rendered by the generic drug company. Plaintiffs wishing to challenge such agreements must allege facts sufficient for a court to evaluate the size and justification, or lack thereof, of the reverse payment.

Endnotes

[1] GSK and Teva have petitioned the Supreme Court for review.
[2] Under the Hatch-Waxman Act, the first generic drug company that files an ANDA with a paragraph IV certification will enjoy a 180-day exclusivity period, where no other generic drug company can compete with the brand name drug.

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