

## Top 5 Developments In Reverse Payments Over The Last Year

*Law360, New York (January 23, 2015, 10:09 AM ET) --*

Reverse payments are one of the most widely debated topics in the antitrust community. And rightly so, considering the many ways in which they continue to remain at the forefront of litigation and legal developments. Last year alone witnessed numerous developments that require some attention.

The goal of this article is to provide a primer on reverse payments and the top five developments impacting these settlements from 2014.

### Reverse Payments in a Nutshell

Under the Hatch-Waxman Act, when a generic drug manufacturer plans on entering the market against a branded pharmaceutical product, it files an abbreviated new drug application to get its drug approved for market. The generic manufacturer can file a Paragraph IV certification, asserting that any patent covering the branded pharmaceutical product is invalid or that the generic will not infringe the brand. In response, the patent holder may initiate a patent-infringement lawsuit against the generic. When parties settle those suits, a “reverse payment” occurs when consideration flows from the branded manufacturer to the generic manufacturer in exchange for the generic manufacturer’s promise to stay out of the market for a period of time.

Following are some of the top developments in the past year.

#### 1. Actavis Applies to Cash Payments

In *Federal Trade Commission v. Actavis Inc.*,<sup>[1]</sup> the U.S. Supreme Court held that reverse payment settlements can violate antitrust laws. This violation depends on various factors, including:

- the anti-competitive effects of the agreement;
- the market power of the players; and



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- the redeeming virtues of the agreement.

But the Actavis court was presented with facts of a “large and unjustified” payment of cash. It therefore left open the question of whether noncash payments could be the basis of antitrust liability.

Two successive decisions took the cash requirement of Actavis at its word. In *Lamictal*,<sup>[2]</sup> the United States District Court for the District of New Jersey upheld the dismissal of an antitrust case on the grounds that the reverse payment arrangement did not meet the large cash payment requirement of Actavis. The United States District Court for the District of Rhode Island followed suit in *In re Loestrin 24*,<sup>[3]</sup> strictly construing the Actavis decision’s requirement of a large and unjustified cash payment.

## **2. Delay Is Not OK, No Matter How You Pay**

Naturally, several courts did not universally support the cash requirement following Actavis. For instance, the United States District Court for the District of Massachusetts reviewed an agreement similar to the one in *Lamictal* and came to a different conclusion.

In the 2013 case, *In re Nexium*,<sup>[4]</sup> the court found that an antitrust violation could occur in the absence of a cash transaction. As long as the parties exchanged something of value, the court found that the Actavis rule of reason analysis should apply. In 2014, the court in *In re Effexor* agreed in principle with the Nexium court that reverse payments can mean noncash consideration, but nonetheless dismissed a complaint based on its conclusion that the plaintiffs had not sufficiently pleaded that the payment was large and unjustified.<sup>[5]</sup>

So where do we stand? Courts have not yet reached a consensus as to whether cash is required in a reverse payment agreement to be anti-competitive. Any company considering such an arrangement should carefully consider the antitrust implications before proceeding.

## **3. Nexium Proceeds to Trial**

In the first case that went to trial following Actavis, the defense came out victorious. *In re Nexium* did not follow the cash requirement, but it did introduce a new wrinkle for those looking to pursue antitrust actions against reverse payment agreements.

The judge in *Nexium* instructed the jury that it could only find the reverse payment anti-competitive if the generic drug maker could have entered the market earlier if the reverse payment agreement never occurred. This interpretation comes from Section 4 of the Clayton Act which requires a showing by a private plaintiff that it suffered actual harm to its business or property as the result of the conduct in question. The court’s ruling posed trouble for the plaintiffs who had to overcome facts that problems at the production facility of the first filer, Ranbaxy, would have prevented it from entering, regardless of the reverse payment. On this standard, the defense prevailed, despite otherwise plaintiff-friendly findings from the jury that the brand manufacturer, AstraZeneca had market power in the relevant market and that the settlement involved a “large and unjustified payment.”

## **4. Europe Joined the Discussion**

The European Commission also considered the validity of reverse payment settlements under European

Union law. In 2013 and 2014, the commission found several such agreements in violation of EU antitrust laws.

- The Danish company Lundbeck received fines of €93,8 million for its part in an agreement to delay the market entry of generic competitors. The generic producers received fines of €52,2 million. Evidence from the negotiations referred to the parties as a “club” and discussed dividing a “pile of \$\$\$” to delay the entry of the generic drugs.
- The commission also fined Johnson & Johnson and Novartis more than €15 million for entering into a “co-promotion” agreement that had the effect of delaying the entry of the generic version of J&J’s Fentanyl.
- Servier and others received fines totaling €427,7 million for entering into an agreement that largely focused on the generic companies agreeing to drop patent litigation concerning the brand-name blood pressure drug Perindopril. The ruling made it clear that competitors cannot engage in anti-competitive behavior by disguising it as a patent settlement.

The Servier decision shows that the commission is willing to go after naked market allocations (such as those in Lundbeck). It also shows that the EC will pursue agreements that arise out of litigation settlements, which courts normally view as pro-competitive. Until the rulings become public, however, we are left to speculate on the commission’s reasoning.

Moreover, manufacturers’ exposure in Europe is not limited to fines from the commission. The European Commission has attempted to facilitate private-damages actions for the past decade, which the European Parliament recently supported by adopting the Directive on Antitrust Damages Actions. The directive is intended to facilitate damages actions in cases that follow on commission findings of liability.

## **5. As Does Canada**

The Competition Bureau in Canada had not announced an official policy regarding reverse payments until September 2014, when it published a paper titled “Patent Litigation Settlement Agreements: A Canadian Perspective.” This paper outlined the Canadian position on reverse payment agreements.

In short, the bureau’s stance is that it may choose to pursue civil and criminal remedies against businesses engaging in anti-competitive reverse payment arrangements. The bureau will look to whether the generic drugs would have entered the market “but for” the reverse payment settlement in question.

Additionally, agreements that violate Section 45 of the Competition Act give rise to private damages actions, which may be pursued in class actions brought by direct or indirect purchasers. The Supreme Court of Canada’s recent “trilogy”[6] of decisions confirms the right of indirect purchasers to sue and further allows them to be present in the same class and represented by the same plaintiffs, at least for the purposes of establishing liability. Even before the Trilogy, class certification standards in Canada were generally thought to be lower than those in the United States.

## **Conclusion**

We see 2015 as the year that will better define what is and is not an illegal reverse payment. Actavis

reignited reverse payments as a hot topic of conversation in antitrust and patent litigation circles. In 2014, those conversations grew hotter as courts divided and the law evolved. What is more, those conversations have caught on abroad, with developments occurring in Europe and Canada.

Pharmaceutical companies and antitrust counsel must remain vigilant in both tracking and shaping the state of the law going forward. This is especially true if they want a say in how these developments play out.

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[1] 133 S. Ct. 2223 (2013).

[2] Lamictal Direct Purchaser Antitrust Litig. v. All Direct Purchaser Action, 18 F. Supp. 3d 560 (D.N.J. 2014).

[3] In re Loestrin 24 FE Antitrust Litig., MDL No. 13-2472-S, DKT No. 116 (D.R.I. 2014).

[4] In re Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367 (D. Mass 2013).

[5] In re Effexor XR Antitrust Litigation, Civ. No. 11-5479 (PGS)(LHG) (D.N.J. Oct. 6, 2014).

[6] Pro-Sys Consultants Ltd. v. Microsoft Corp., Sun-Rype Products Ltd. v. Archer Daniels Midland Co., Infineon Technologies v. Option Consommateurs

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