

5 Red Flags In Pharmaceutical Settlements

Law360, New York (May 13, 2014, 1:05 PM ET) -- When the U.S. Supreme Court decided *Federal Trade Commission v. Actavis Inc.*[1] last year, it opened the door to antitrust challenges to settlements between generic and branded pharmaceutical companies to resolve patent litigation under the Hatch-Waxman Act. Although Actavis offers some guidance as to what constitutes an “illegal” reverse payment, the court largely left it to the lower courts and the FTC to sketch the contours of permissible reverse payments. As a result, interested parties can now expect a higher probability for close scrutiny of those settlements. It is important to understand the “red flags” likely to pique the interest of scrutinizing eyes.



Ryan Marth



Matthew McFarlane

Importantly, the risks to settling parties are not limited to a potential FTC investigation. State attorneys general may investigate and challenge agreements under state laws, which may impose more strict liability standards than federal law.[2] In addition, Actavis has led to an increase in the number of challenges to reverse payment settlements by private plaintiffs, including several groups of direct purchasers suing under federal law (large retailers and wholesalers) and indirect purchasers suing under state laws (third-party payors and individual consumers).

Are there guideposts to help companies embroiled in Hatch-Waxman litigation determine whether they can settle their case with terms that include some form of consideration flowing from the branded manufacturer to the generic without antitrust scrutiny? There are, and below, we discuss five important red flags that might bring unwanted attention to a settlement.

1. Large Consideration Paid From Brand to Generic

The Supreme Court’s prerequisite for reverse-payment liability was a “large, unexplained payment” from brand to generic. The court did not specify how “large” a payment would need to be to constitute an illegal settlement.

Nor did the court specify whether the “large, unexplained payment” had to be cash. Of course, past agreements in the industry featured other forms of consideration, like licensing, distribution, or supply agreements, an agreement to name the abbreviated new drug application applicant the “authorized

generic” of the branded firm, or an agreement by the branded firm not to name an authorized generic. Actavis did not answer whether settlements that include valuable consideration like this to the generic company are inherently suspect.

The lower courts have provided some guidance — albeit conflicting — as to what might constitute a “payment.” In *In re Lamictal Direct Purchaser Antitrust Litigation*, the court concluded that a covenant by the branded manufacturer to refrain from marketing an authorized generic to compete with the ANDA applicant during the ANDA applicant’s exclusivity period was not a “reverse payment” subject to antitrust scrutiny.[3] The court reasoned that Actavis applied only to settlements involving cash, leaving untouched those settlements that have strictly non-monetary terms. The court distinguished as dicta earlier opinions that arguably opened the door to scrutiny of non-monetary consideration.[4]

The FTC and private plaintiffs have taken a more expansive view of Actavis, pushing ahead with claims that certain forms of nonmonetary consideration can generate liability.[5] This activity compels parties contemplating settlement to closely examine nonmonetary consideration when evaluating the prospects of antitrust scrutiny to a potential settlement.

And just how large is “large”? We simply don’t know. There has been no formal guidance from the courts or the FTC as to the magnitude of consideration that would trigger scrutiny. As an informal guide, private lawsuits filed after Actavis have alleged a value of brand-to-generic consideration between \$75 million and \$125 million. While those allegations can hardly be read as establishing a clear threshold for antitrust scrutiny, they shed some light at least on what the private bar views as “large.”[6]

2. Significant Delay to Generic Entry

Reverse-payment cases define the harm to competition as the generic refraining from entering the market. It therefore follows that the length of time in which the generic agrees to stay off the market is a key factor in assessing whether a Hatch-Waxman settlement could potentially be viewed as anti-competitive. Thus, a long delay between settlement and agreed-upon entry, or an entry date that is only slightly before patent expiration, could raise red flags with government or private enforcers. A survey of FTC enforcement actions and post-Actavis private actions confirms that the length of delay is an important consideration in whether to challenge an agreement.[7]

3. External Indications of Patent Weakness

A patent perceived to be “weak” is likely to provoke the suspicion of government and private enforcers. In *Actavis*, the court implicitly endorsed the view that a patent does not give the patent holder the right to exclude others, but rather the right to try to exclude others. Thus, the court reasoned that a settlement could be anti-competitive even if the generic entered before a patent expired, especially if the patent was viewed as “weak.” At the same time, the court did not endorse the view — at least not in the context of a challenge under Section 5 of the FTC Act — that a court had to hold a “mini-trial” to assess the patent’s strength.

The law presumes that all issued patents are valid, but what determines whether a patent is “strong” or “weak”? In Actavis, as in other FTC enforcement actions, the FTC looked to extrinsic factors — such as projections of generic entry by analysts or in business documents — to assess the strength of the patent.

Some cases may include preliminary rulings on patent scope or validity, information that might constitute direct evidence of the strength of the patent. And as in other government investigations, internal documents may be key. In particular, analysts’ reports — especially those that assess the likelihood of generic entry — are easily digestible and provide what enforcers believe to be “honest” assessments of the commercial landscape, including patent-protected assets. Multiple ANDA filers challenging a patent could also indicate weakness by showing that several firms shared the independent belief that each could prevail in patent litigation.

4. Settlements Regarding Formulation Patents

Enforcers may also view settlements in litigation over formulation patents as suspect. In contrast to a composition patent that covers the active compound, a formulation patent covers only the preparation of the compound into the form administered to a patient.

Composition patents usually issue by pointing to an identifiable novel or nonobvious improvement over the prior art. Formulation patents, on the other hand, simply package a compound into a particular form that in most cases had been used for other compounds in the past, raising obviousness concerns. For this reason, the industry generally views formulation patents covering a drug to be “weaker” than the corresponding composition patents.

It does not help that branded manufacturers have turned to formulation patents as a tool to delay generic entry. In a practice often referred to as “evergreening,” a branded manufacturer might introduce a slight change to the formulation that, if separately patented, could extend patent protection and exclude generics that are no longer equivalent to the prescribed brand. Because of this arguably nefarious history, settlements that relate only to formulation patents run an increased risk of attracting the attention of the FTC or private enforcers.

5. Covenants Relating to Authorized Generics

Settlement terms relating to authorized generics are particularly likely to attract antitrust scrutiny in recent years. An authorized generic is a generic form of a pharmaceutical treatment, which is produced either by the branded manufacturer itself or by a selected generic manufacturer, pursuant to a license from the branded firm. Authorized generics can potentially be pro-competitive, when the authorized generic competes in the generic market alongside other generic firms or introduces a generic form of a drug that would not otherwise exist.

In the view of the FTC and private plaintiffs, however, authorized generics can be used anti-competitively in Hatch-Waxman settlements. For example, the branded firm might agree to forego

producing an authorized generic as part of its consideration to the settling generic. Or the branded manufacturer might simply name the generic challenger as its authorized generic as part of a deal. Either way, a government enforcer or private plaintiff could view this type of an arrangement as an attempt to deprive the marketplace of an additional generic competitor. Thus, even though the courts have yet to endorse the theory that a settlement agreement involving an authorized generic constitutes a “reverse payment,” there is sufficient interest in these types of settlement agreements for settling parties to consider the risk of an antitrust suit or investigation.

Conclusion

Actavis was clear that every Hatch-Waxman settlement is different. There are no clearly defined categories of individual settlement provisions that will or will not attract antitrust scrutiny. And while Actavis acknowledges that it does not alter the courts’ general public policy interest in favor of settlement, Actavis and other challenges to generic-branded settlement agreements stress that settling parties should take seriously the prospect of antitrust scrutiny of their agreements as part of a comprehensive risk management strategy.

—By Ryan W. Marth and Matthew B. McFarlane, Robins Kaplan Miller & Ciresi LLP

Ryan Marth is a principal in Robins Kaplan's Minneapolis office. Matthew McFarlane is a principal in the firm's New York office. The authors would like to thank Mitha V. Rao, an associate in the firm's Minneapolis office, for her assistance in assembling this article.

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[1] Federal Trade Comm’n v. Actavis, Inc., 570 U.S. ___, 133 S.Ct. 2223 (2013).

[2] The California Attorney General submitted an amicus brief in a private challenge to a reverse-payment settlement, arguing that reverse payments are illegal per se under California law and that, even if the court adopted a rule-of-reason standard, it should cabin the defenses available to defendants. Br. of Amicus Curiae Cal. Atty. Gen., In re Cipro Cases I & II, No. S198616 (Cal. Mar. 18, 2014).

[3] In re Lamictal Direct Purchaser Antitrust Litig., 2014 U.S. Dist. LEXIS 9257, at *20-25 (D.N.J. Jan. 24, 2014).

[4] See In re Lipitor Antitrust Litig., 2013 U.S. Dist. LEXIS 126468 (D.N.J. Sept. 5, 2013) (allowing amendments to complaint to include allegedly anticompetitive nonmonetary payments); In re Nexium (Esomeprazole) Antitrust Litig., 2013 U.S. Dist. LEXIS 129696, at *15 (D. Mass. Sept. 11, 2013)(reconsidering dismissal in light of Actavis based on monetary and non-monetary consideration).

[5] See Br. of Amicus Curiae FTC, *In re Effexor Antitrust Litigation*, No. 11-cv-5479 (D.N.J. Aug. 16, 2013).

[6] See, e.g., *Compl. Am. Sales Co., LLC v. Endo Pharmaceuticals, Inc.*, No. 3:14cv22 (N.D. Cal.) (Between \$96 million and \$261 million of free product, less a royalty on the generic's sales during the exclusivity period); *Compl., United Food & Commercial Workers Local 1776 v. Teikoku Pharma. USA*, No. 3:13cv5257 (N.D. Cal.) (\$96 million in free product, plus agreement not to market authorized generic, valued at \$24 million); *Compl., City of Providence v. Abbvie*, 1:13cv292 (E.D. Pa. Sept. 26, 2013) (At least \$77 million in royalties in exchange for agreement not to license authorized generic); *Compl., Int'l Union of Operating Engineers Local 132 v. Medicis Pharmaceuticals Corp.*, 2:13cv5108 (\$63 million in payments under a joint-development agreement plus 50% of profits from jointly developed products).

[7] See, e.g., *Compl. Am. Sales Co., LLC v. Endo Pharmaceuticals, Inc.*, No. 3:14cv22 (N.D. Cal. Jan. 7, 2014) (Generic Lidoderm entry 16 months after settlement but 6 months before patent expiration); *Compl., Giant Eagle v. Pfizer Inc.*, No. 3:13-cv-2478 (D.N.J. Apr. 18, 2013) (alleging entry after patent expiration); *Compl., Plumbers & Pipefitters Local 178 Health & Welfare Trust v. Teikoku Pharma USA, Inc.*, No. 3:13-cv-5938 (N.D. Cal. Dec. 23, 2013) (alleging 7 years between settlement and entry, which could occur 6 months prior to patent expiration); *Compl., City of Providence v. Abbvie*, 1:13cv292 (E.D. Pa. Sept. 26, 2013) (Approximately 7-year alleged delay in entry of generic Niaspan, which occurred 4 years before expiration).