CLIENT ALERT

NJ Federal Court Says Pharmaceutical Manufacturers Can Agree to Keep Generics Off The Market Without Antitrust Scrutiny If No Cash Changes Hands

Jan.29.2014

On January 24, 2014, a New Jersey federal judge dismissed an antitrust class action against GlaxoSmithKline LLC and Teva Pharmaceutical Industries Ltd., reasoning that the recent Supreme Court decision in *FTC v. Actavis*, which changed the antitrust standards for certain deals between pharmaceutical manufacturers, did not apply because the settlement did not contain a cash payment from the brand-name drug maker to a generic competitor— a so-called "reverse payment." Indeed, the New Jersey Court held that "*Actavis* applies only to 'reverse payments' of money."

The decision in *In Re Lamictal Direct Purchaser Antitrust Litigation*[1] suggests that settlement agreements between brand and generic pharmaceutical manufacturers that keep the generic off the market for some period of time prior to expiration of the patents at issue, but which do not involve the payment of cash to the generic, should withstand antitrust scrutiny. The lesson for drug manufacturers seeking to settle patent litigation is clear: split time, not money.

This case has three facets that render the decision particularly interesting and important to drug manufacturers. First, the brand drug at issue was a very lucrative epilepsy drug that from 2007-08 had domestic sales of more than $2 billion. Thus, forestalling generic competition had substantial value. Second, the generic company appeared to be winning the underlying patent litigation—the trial judge had invalidated Claim 1 of the brand patent as anticipated by prior art—which led to immediate settlement discussions. Third, the court ignored the fact that the settlement agreement contained a provision that GSK would not enter the market with its own authorized generic (the so-called "no authorized generic" or "no-AG" provision). According to the court, the resulting settlement "allowed Teva to market generic lamotrigine before the relevant patent expired and ensured that once it did so, its generic tablets and chewables would not face competition from GSK's own 'authorized generic' for a certain period of time." Despite these facts, the court held that the antitrust laws did not preclude the settlement.

The underlying lawsuit, which had originally been dismissed for failure to state a claim, was on remand from the Third Circuit for reconsideration in light of the Supreme Court's decision in *Actavis*.

On remand, U.S. District Judge William H. Walls focused on the terms of GSK/Teva settlement agreement. That agreement contained three key components:

1. **Chewables**: Teva was permitted "early entry" 37 months before expiration of GSK's patent. Moreover, GSK supplied chewables to Teva for sale even before the FDA approved Teva's ANDA for lamotrigine chewables.
2. **Tablets**: Teva was permitted to sell tablets during an "early entry" period of six months before expiration of the GSK patent.
3. **No Authorized Generics**: GSK agreed not to launch its own generic version during the 180-day first-filer exclusivity period.

Applying *Actavis* to the terms of the settlement agreement between GSK and Teva, Judge Walls affirmed his earlier dismissal, holding that the Supreme Court's landmark decision in *Actavis* requires antitrust scrutiny to be applied only to deals in which a brand-name drug maker pays cash to a competitor to keep a rival generic off the market. Because the settlement agreement between GSK and Teva—which delayed Teva's production of a generic form of GSK's billion dollar bipolar and epilepsy medicine—did not involve such a "reverse-payment," the judge determined it was proper to again dismiss the direct purchasers' claims.

Before Actavis, Third Circuit Precedent Applied Antitrust Scrutiny to Reverse Payments

Prior to the Supreme Court's decision in *Actavis*, the Third Circuit held in a case known as *K-Dur* that antitrust scrutiny should apply only to settlements in which an accused infringer was paid cash not to compete. When the trial court first reviewed the GSK/Teva settlement prior to *Actavis*, the court held that GSK's promise not to launch its own authorized generic during Teva's exclusivity period did not amount to a "reverse payment" under *K-Dur.* Based on this precedent and the absence of a cash payment, Judge Walls initially dismissed the complaint, stating: "This court will not stretch the holding of *K-Dur* beyond the contours articulated by the Third Circuit." The plaintiffs appealed, but the Third Circuit granted a defense motion to stay the case pending the Supreme Court's decision in *Actavis.*

The high court issued its *Actavis* ruling in June 2013, replacing the so-called "quick-look" test the Third Circuit applied in *K-Dur* with the more robust "rule of reason" analysis typically applied in antitrust cases. Thereafter, the Third Circuit remanded *Lamictal* for reconsideration in light of *Actavis.*

Actavis Scrutiny Applies Only to Patent Settlements that Contain Reverse Payments of Money

On remand, the trial court held that, as in *K-Dur*, "*Actavis* requires scrutiny only of patent settlements that contain reverse payments," and those payments must involve "an exchange of money." The two main holdings were set forth in the headings used by Judge Walls in his memorandum opinion:

1. *Actavis Scrutiny Applies Only to Patent Settlements that Contain Reverse Payments*
2. *Actavis Applies Only to "Reverse Payments" of Money*

In ruling that reverse payments are required to trigger antitrust scrutiny, Judge Walls noted that, in *Actavis*, "[t]he [Supreme Court's] focus is on reverse payments from the very first words of the opinion." The *Lamictal* opinion emphasizes the high court's consistent focus on the unique nature of reverse payment settlements. Moreover, the court noted that, in *Actavis*, the Supreme Court expressly exempted "early entry" settlements, where a generic enters the market before the brand patent expires, without a reverse payment. As Justice Breyer wrote in *Actavis*:

> [T]he fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit. They may, as in other indus-tries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point.[2]

Relying on this language, Judge Walls concluded that, "[a]t the very least, then, one kind of settlement may be free from antitrust scrutiny: one consisting *solely* of an early entry provision."

Moreover, the trial court rejected arguments that the term "reverse payment" need not be limited to money, even though as defined by *Black's Law Dictionary*, "payment" includes "some other valuable thing accepted in partial or full discharge of an obligation." Instead, the trial court relied on Supreme Court language in *Actavis*, including the following definition: "[R]everse payment settlements—e.g., in which A, the plaintiff, *pays money* to defendant B" (emphasis added).

Although plaintiffs argued that GSK stood to make tens of millions of dollars by keeping the generic off the market, and that GSK's agreement to withhold authorized generic competition was likely worth tens of millions of dollars to Teva, the court refused to equate these facts with a "payment." Despite its holding that there was no "payment" – and thus, no reason to subject the settlement to antitrust scrutiny – the trial court nevertheless went on to apply the tougher "rule of reason" test required by *Actavis*, but reached the same conclusion, that GSK and Teva did not violate the antitrust laws.

Judge Walls analysis differs substantially from that of the FTC. The FTC takes the exact opposite position when it comes to whether cash is a prerequisite to antitrust scrutiny. The FTC argued in another case in the same court that, "nothing in the [*Actavis*] opinion suggests that the Court meant to limit its ruling to payments in cash, nor would such an artificial limitation make economic sense."[3]

Question: What Does In Re Lamictal Direct Purchaser Antitrust Litigation Mean for Drug Manufacturers? Answer: Split Time, Not Money

This ruling sends a clear signal that forms of settlement other than reverse payments may be explicitly exempt from antitrust review. In one way, the opinion is consistent with what the FTC has been saying for years: that resolving these patent disputes by "splitting time" – that is allowing early entry of generic competition – is a reasonable and appropriate way to avoid anti-competitive effects. To that end, the FTC has argued:

> [W]hen the parties in Hatch-Waxman patent litigation settle with an agreement that merely sets a date for the generic patent challenger's market entry before patent expiration, without more, there is nothing to suggest that this familiar settlement form reflects anything other than arms-length bargaining between adverse parties based on expectations regarding the likely outcome of the litigation.[4]

However, Judge Walls did not address one aspect of the settlement that may raise additional antitrust concerns – the agreement by GSK not to enter the market with its own authorized generic (the so-called "no authorized generic" or "no-AG" provision). In a footnote, the trial court anticipated that both the plaintiffs and the FTC might argue that the antitrust "carve-out" for settlements that involve early entry does not extend to agreements that delay authorized generics.[5] In fact, the FTC has taken the position that "no-AG" provisions may have anti-competitive effects, and therefore hurt consumers. In a 2011 report, the FTC concluded:

> [A]s a consequence of an authorized generic's significant negative impact on a generic's revenues, some brand-name companies have used agreements not to launch an authorized generic as a way to compensate an independent generic in exchange for the generic's agreement to delay its entry. The frequency of this practice and its profitability may make it an attractive way to structure a pay-for-delay settlement, a practice that causes substantial consumer harm.[6]

As a result, the FTC has argued that "the no-authorized-generic commitment presents the same antitrust concern as the reverse payments the Supreme Court considered in *Actavis*."[7] Despite the FTC's position on "no-AG" agreements, the *Lamictal* opinion fails to address explicitly that aspect of the settlement between GSK and Teva. So while *In Re Lamictal Direct Purchaser Antitrust Litigation* may be a green light for drug manufacturers to enter into "early entry" settlement agreements without reverse payments, it remains an open question whether "no-AG" provisions will be able to skirt antitrust scrutiny in future cases or on appeal.

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[1] *In Re Lamictal Direct Purchaser Antitrust Litigation,* No. 12-cv-995 (D.N.J. Jan. 24, 2014).

[2] *F.T.C. v. Actavis*, 133 S. Ct. 2223, 2237 (2013).

[3] Brief of Amici Curiae F.T.C., at 6, *In re Effexor XR Antitrust Litigation*, No. 3:11-cv-05479 (D.N.J. Aug. 14, 2013).

[4] Id. at 7.

[5] *In Re Lamictal Direct Purchaser Antitrust Litigation,* at 12 (footnote 4).

[6] "Authorized Generic Drugs: Short-Term Effects and Long-Term Impact," at 8-9. Federal Trade Commission (2011), 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

[7] Brief for Amici Curiae F.T.C., at 6, *In re Effexor XR Antitrust Litigation*, No. 3:11-cv-05479 (D.N.J. Aug. 14, 2013).

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