

Third Circuit Holds Non-Cash Consideration – Such As “No Authorized Generic” Agreements – Can Constitute Unlawful “Pay For Delay”

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First appellate court decision applying *FTC v. Actavis* (S.Ct. 2013).

Court finds rule of reason analysis should be applied where non-cash consideration – including agreement not to launch authorized generic – flows from patent holder to alleged infringer.

Summary

In *King Drug Company of Florence, Inc. v. Smithkline Beecham Corp. d/b/a GlaxoSmithKline*, No. 14-1243 (3d Cir. June 26, 2015), the Third Circuit was confronted with two interrelated issues: First, whether non-cash payments fell within the Supreme Court’s ruling in *Actavis*. Second, even if certain non-cash payments were subject to rule of reason scrutiny, could a patent holder’s commitment not to enter the market with an authorized generic (“no-AG agreement”) constitute an “unexplained large reverse payment” warranting antitrust scrutiny. On both issues, the Third Circuit answered in the affirmative. The Court held that nothing in *Actavis* limited its scope to cash payments. As to no-AG agreements, the Court stated that absent such agreements, patent holders would have an economic incentive to introduce an authorized generic, and generic companies would attempt earlier generic entry either by entering “at risk” or by successfully defending against the infringement litigation. Thus, the Court reasoned, a no-AG agreement may have anticompetitive effects that would need to be affirmatively justified by offsetting procompetitive benefits.

Factual Background

GlaxoSmithKline (“GSK”) introduced Lamictal, a blockbuster drug that treats epilepsy and bipolar disorder, and held a patent for its active ingredient, lamotrigine. In 2002, Teva filed the first Paragraph IV ANDA with the FDA to market generic lamotrigine alleging, as it was required to do under the Hatch-Waxman Act, that the GSK patent was invalid or not infringed. To incentivize successful patent challenges, Hatch-Waxman affords “first filers” such as Teva a 180-day exclusivity period vis-à-vis other potential generic entrants.

The New Jersey district court ruled in Teva’s favor as to GSK’s main patent claim. Before that court ruled on the remaining patent claims, GSK and Teva settled in 2005. Under the settlement, GSK would allow Teva to enter the market with generic lamotrigine tablets (GSK’s \$2 billion product at the time) six months before GSK’s exclusivity would expire. GSK would also allow Teva to enter the market with a generic version of a less popular version of the drug, the chewable tablets (GSK’s then-\$50 million product), much earlier (37 months before patent

expiration). As part of the settlement, GSK agreed not to market its own generic, an “authorized generic,” until after Teva’s 180-day exclusivity period expired.

Plaintiffs’ Class Action

A putative class of direct purchasers alleged that GSK and Teva’s settlement fell under the Supreme Court’s *Actavis* standard for “pay-for-delay” cases and violated Sherman Act Section 1 (illegal agreement) and Section 2 (monopolization or attempted monopolization).

Plaintiffs alleged that Teva would have launched its generic version “at risk” after receiving FDA approval (which occurred in August 2006, i.e. nearly two years before Teva’s agreed main entry date under the settlement), had Teva not been “induced” – by the no-AG commitment made by GSK – to delay its generic entry, thereby guaranteeing Teva a “monopoly” for the 180-day exclusivity period.

The lower court, which oversaw the patent litigation and approved the settlement, dismissed plaintiffs’ claims because it found, inter alia, that the Supreme Court’s *Actavis* decision applies only to cash “reverse payments.”

The Third Circuit’s Decision

The Third Circuit reversed, holding that no-AG agreements, like the one between GSK and Teva, should be subject to antitrust scrutiny under the full “rule of reason” framework adopted in *Actavis*. Quoting from the majority opinion in *Actavis*, the Third Circuit held that non-cash payments or commitments flowing from the patent holder to the alleged infringer, such as a no-AG agreement, may be “an unusual, unexplained reverse transfer of considerable value” that falls under the “pay-for-delay” standard.

The Court observed that such an agreement has significant monetary value to a “first-filer” generic.¹ The Court also stated that “launching an authorized generic would seem to be economically rational” from the patent holder’s perspective unless the benefits of settling the patent litigation – thus avoiding the risk of earlier generic entry – outweighs the foregone authorized generic revenues.

The Court reasoned that a mere agreement on an “early-entry date alone” may simply reflect the parties’ compromise assessment of the strength of the patent. But, the Court stated, the additional compensation of a no-AG promise may cause the generic challenger to accept a later entry date than it would otherwise have chosen, to the detriment of consumers.

The Court rejected defendants’ contentions that a no-AG agreement was simply an exclusive license that is specifically permitted under patent law, and hence was not “unusual” under the *Actavis* standard. The Court reasoned that the license was not exclusive because the patent holder would continue to market the branded drug. Moreover, the Court reasoned, a no-AG agreement, unlike the usual exclusive license, could not be said to promote the patent holder’s incentive to innovate because it primarily benefits the licensee.

¹ Relying on an FTC study, the Court noted: “...a comprehensive FTC study suggests that having to compete with an authorized generic will likely both cut the generic’s sales and force down its price: ‘the presence of authorized generic competition reduces the first-filer generic’s revenues by 40 to 52 percent, on average.’” FTC, *Authorized Generic Drugs: Short-Term Effects and Long Term Impact* iii (2011), available at <http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf>.

Key Takeaways

- *Actavis'* pay-for-delay analysis is not limited to ANDA settlements involving cash payments. Parties entering into such settlements should be prepared to defend non-cash consideration flowing to the alleged infringer on the ground that they are not “large” or “unusual” and are justified by commercial considerations other than forestalling earlier generic entry.
- No-AG provisions are contained in many ANDA settlement agreements. It remains to be seen whether other courts will agree with the Third Circuit’s rejection of the defense that a no-AG agreement is merely an exclusive license expressly permitted under the patent laws and hence not an “unusual” or “unexplained” way for a patent holder to reap the rewards of its invention. In this regard, the Third Circuit’s holding suggests its preference for assuring short term benefits to consumers at the possible expense of longer term, but more difficult to measure, diminution of the incentive to innovate. It is perhaps worth noting that in providing the first-filer generic with the incentive of a 180-day exclusive marketing period, Congress was willing to forego the benefits of competition from other generics but the Third Circuit now insists upon requiring the patent holder to retain its right to compete with the first filer during that same 180-day period.²
- It is also worth noting that the Third Circuit ruling vacates the lower court’s grant of a *motion to dismiss*, in which all of plaintiffs’ factual allegations (including that the generic would have launched “at risk” and that the brand company would have launched an authorized generic absent the agreement) must be accepted as true. Whether plaintiffs can prove those allegations, and whether defendants will be able to show legitimate justifications for the settlement terms, remains to be seen. These issues may arise again in connection with a motion for summary judgment later in the case, perhaps with a different result. For example, GSK may renew its argument that the settlement agreement left it free to compete with Teva during the 180-day period by lowering the price of its branded drug and that it in fact did compete in that fashion.
- The Third Circuit’s decision leaves open the question whether an agreement not to launch an authorized generic *prior to* the first-filer generic’s 180-day exclusivity period would be permissible. During that time, the parties could not have competed, and such an agreement not to undermine later generic entry may be viewed in a more favorable light.

² Indeed, as GSK pointed out in its brief, Congressman Waxman himself believed that authorized generics should be prohibited because they undermined the exclusivity incentive offered to first filers in the Hatch-Waxman Act: “I don’t think we should again allow the frustration of the intent of the law’ by allowing brand companies to sell authorized generics.” GSK Br. at 9 n.6 (also citing Letter from Rep. Henry A. Waxman to Deborah Majoras, Chairman, Fed. Trade Comm’n (Sept. 13, 2005) (requesting that the FTC study authorized generics because the “rise of authorized generics raises serious competitive issues”)).

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