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E-ALERT | Antitrust / Pharmaceuticals

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FTC BRINGS ITS FIRST POST-*ACTAVIS* SUIT

The Federal Trade Commission has brought its first suit alleging anticompetitive conduct in connection with the prosecution and settlement of pharmaceutical patent litigation since the Supreme Court's June 2013 decision in *FTC v. Actavis*. Although two commissioners dissented from the decision to issue the complaint (Ohlhausen and Wright), the action reveals that the Commission's interest in scrutinizing settlements between innovator pharmaceutical companies and generic companies remains high. In particular, this action appears to signal an expansion of the Commission's enforcement to settlements involving non-cash consideration as "payment" for delayed entry under *Actavis* and a strategy to couple that challenge with an allegation of sham litigation.

ANDROGEL I (AKA *ACTAVIS*)

In June 2013, the Supreme Court issued its first-ever decision in a case involving so called "reverse payments" between innovator pharmaceutical companies and generic pharmaceutical companies. The majority opinion by Justice Stephen Breyer in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), established that settlement agreements involving payments from an innovator to a generic company in excess of saved litigation costs are not presumptively illegal but are instead subject to a "rule of reason" analysis. Justice Breyer explicitly left it to the lower courts to define the contours of the rule of reason analysis in this context.

In *Actavis*, the innovator companies had settled patent litigation over the topical testosterone gel, AndroGel, by allegedly agreeing to pay three generic companies millions of dollars for marketing and other services that the generics agreed to perform. The Eleventh Circuit affirmed the Northern District of Georgia's dismissal of the FTC's complaint for failure to state a claim, finding that "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012). The Supreme Court reversed and remanded, and the case is now proceeding in the Northern District of Georgia with fact and expert discovery in advance of a September 2015 deadline for filing summary judgment motions.

ANDROGEL II

Actavis involved a challenge to agreements between the AndroGel innovators and Actavis, Paddock, and Par. On September 8, 2014, the Commission filed a complaint in the Eastern District of Pennsylvania (Kelly, J.) against the AndroGel innovators and a different generic company (Teva Pharmaceuticals USA, Inc.). The Commission's most recent complaint asserts two claims under Section 5 of the FTC Act, 15 U.S.C. §45(a): monopolization against the innovator defendants based on alleged sham patent litigation and restraint of trade against all defendants based on the alleged anticompetitive settlement agreement.

The Commission alleges that, during prosecution of a patent application involving formulations of AndroGel, the patentees overcame a rejection of the application as obvious over prior art by limiting the patent to a specific type of "penetration enhancer." As a result, the innovators knew, according to the Commission, that the formulations of Teva and Perrigo that allegedly designed around the patent by using different penetration enhancers, did not infringe the patent. The Commission thus alleges that the patent infringement suits against Teva and Perrigo were "sham litigations." The Commission then alleges that the agreement to settle the Teva patent litigation constituted an illegal reverse payment because, according to the Commission, Teva agreed not to delay the marketing of its version of AndroGel in exchange for an allegedly "large and unjustified" payment. According to the Commission, the alleged payment took the form of an authorized generic supply agreement for an unrelated product (TriCor). The Commission seeks injunctive, declaratory and "other equitable relief… (including restitution or disgorgement)."

POINTS FOR CONSIDERATION

A few points bear emphasis:

- The Commission remains very interested in establishing that non-cash consideration qualifies as a "payment" under *Actavis*. The Commission's choice of a court in the Third Circuit—where dismissal of the claims in *In re Lamictal Antitrust Litigation* on the ground that the "no authorized generic" agreement is not a "payment" under *Actavis*, is currently on appeal—suggests that the Commission believes that the courts will ultimately agree with the Commission's position that non-cash consideration subjects a settlement to antitrust scrutiny.
- The fact that the first post-*Actavis* case brought by the Commission includes allegations of sham litigation based on an allegedly weak formulation patent appears to suggest that the Commission has seized on Justice Breyer's reference to "the patent-related policy of eliminating unwarranted patent grants." *Actavis*, 133 S. Ct. at 2233.
- It appears that the FTC is trying to create a pathway to prevail under *Actavis even if* the alleged payment arises from a bona fide agreement involving fair value for services rendered. The Commission appears ready to argue that whether the business agreement makes independent business sense is irrelevant because, according to the Commission's argument, there never should have been litigation—or a settlement—in the first place.

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Covington & Burling has deep expertise in the unique business and regulatory environment under which Hatch-Waxman patent settlements are negotiated. Covington attorneys have been retained to counsel pharma clients in the negotiation of numerous settlements, have tried a reverse payment antitrust case brought by the FTC to conclusion, winning outright dismissal of the case (*FTC v. Schering Plough*), and have defended several antitrust cases alleging reverse payment patent settlements, including *In re Nexium Antitrust Litigation*, *In re Wellbutrin XL Antitrust Litigation*, and *In re K-Dur Antitrust Litigation*.

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