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CLIENT ALERT

First Circuit Joins Third Circuit in Holding That *FTC v. Actavis* Applies to Non-Cash Payments

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In a closely watched "reverse payment patent settlements" case, *In re: Loestrin 24 Fe Antitrust Litigation*, the U.S. Court of Appeals for the First Circuit has joined the Third Circuit and several district courts in holding that the U.S. Supreme Court's decision in *FTC v. Actavis*, 133 S. Ct. 2223 (2013) applies to non-monetary settlements. The First Circuit reversed the district court's dismissal and held that *Actavis* applies to non-cash payments as well as cash payments.

The case involves brand-name drug manufacturer Warner Chilcott and its patents for Loestrin 24 Fe, an oral contraceptive. After Watson Pharmaceuticals, Inc. and Lupin Pharmaceuticals, Inc. attempted to launch a generic version, Warner sued for patent infringement. Both lawsuits ultimately ended in settlement agreements. Warner and Watson entered into the first settlement agreement in January 2009, whereby Watson would delay entering the market in exchange for the following:

1. Warner would not market, supply, or license an authorized generic version of Loestrin 24 during Watson's first 180 days of marketing its generic Loestrin 24.
2. As of January 22, 2014, Watson would have a non-exclusive, fully paid, worldwide, royalty-free irrevocable license to market Loestrin 24.
3. Warner would pay Watson annual fees and a percentage of net sales in connection with Watson's co-promotion of another Warner hormone therapy product.
4. Watson received an exclusive right to earn brand sales of another Warner oral contraceptive still in development.
5. No other generic manufacturer of Loestrin 24 would receive a license to manufacture Loestrin 24 until at least 180 days after Watson entered the market.
6. Watson could enter the market prior to January 22, 2014 if another generic manufacturer entered the market before Watson.

A year and a half later, Warner and Lupin entered into a similar settlement agreement that ended Lupin's later-filed suit. Lupin agreed that it would delay entering the Loestrin 24 market in exchange for a non-exclusive license for another Warner oral contraceptive; the right to sell a generic version of another Warner medication if a generic version was launched by another manufacturer in the United States; and attorney's fees.

A class of direct purchaser plaintiffs and a class of end payor plaintiffs sued Warner, Watson, and Lupin, alleging that these two alleged reverse-payment agreements violated the antitrust laws. The defendants moved to dismiss on multiple grounds, and the district court granted the motion, on the basis that *Actavis* applied only to monetary reverse payments. The district court relied in part on language from *Actavis* it interpreted to show the Supreme Court was "fixated" on cash.

The First Circuit reversed and remanded, concluding that "antitrust scrutiny attaches not only to pure cash reverse payments, but to other forms of reverse payment that induce the generic to abandon a patent challenge, which unreasonably eliminates competition at the expense of customers." (Slip opn. at 25.) Antitrust law "has consistently prioritized substance over form," the

court reasoned, and a contrary ruling could "give drug manufacturers carte blanche to negotiate anticompetitive settlements so long as they involve non-cash reverse payments." (*Id.* at 25-26.) As the court noted, a majority of courts to have considered the issue—including the Third Circuit in *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015)—have reached the same conclusion concerning non-cash payments.

The decision leaves open the issue of the level of detail and type of allegations required to plead that a non-monetary settlement constitutes a large and unjustified reverse payment under *Actavis.* The First Circuit offered only that a complaint need not include precise calculations, but must contain information sufficient to estimate the value of the term and determine whether it is large and unjustified. (Slip opn. at 31-32.) In addition, the First Circuit noted that the "size of the reverse payment, particularly as it relates to potential litigation expense, is central to the antitrust query." (*Id.* at 29.)

Among many questions left open by the First Circuit's decision, the most important may be how district courts will apply *Twombly* to assess the specificity of an antitrust challenge to a reverse payment patent settlement.

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