Antitrust Implication of Recent FTC Patent Related Agreement

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In recent years, the Federal Trade Commission (FTC) has refocused its efforts on the interplay between the patent system and antitrust law, particularly in the pharmaceutical industry. While most of this focus has manifested in actions focused on so-called "pay-for-delay" settlements that prolong a brand name pharmaceutical product's market power, such as its victory in *FTC v. Actavis*, 133 S. Ct. 2223 (2013), the FTC has also focused on the interplay between marketers of generic products.

For example, the FTC recently reached an agreement and consent orders with Concordia Pharmaceuticals Inc. (and a related entity) a manufacturer of brand name pharmaceuticals, and Par Pharmaceutical, Inc. (and two related entities), a manufacturer of generic pharmaceuticals. The proposed consent orders, which remain subject to final approval, settle the FTC's allegations that Concordia and Par entered into an unlawful agreement not to compete related to generic versions of the prescription drug Kapvay, which is used to treat attention deficit hypersensitivity disorder.

The FTC alleged that, in 2013, five weeks before the expiration of Concordia's patent covering Kapvay, Concordia entered into an agreement with Par that granted Par a license effective one week before the expiration of the patent. Concordia agreed not to market an authorized generic version of Kapvay for five years in exchange for 35-50% of the net profits from the sale of Par's generic Kapvay product. In its complaint, the FTC alleged that the license agreement had anticompetitive effects, including decreased competition and increasing prices for consumers. FTC studies have found that competition from authorized generic drugs (i.e. generic drugs produced by the manufacturer of the brand-name analogue) result in lower prices and drastically lower revenues for the first generic entrant to the market.

Under the terms of the proposed consent orders, Concordia is required to relinquish any right to payment under its license agreement with Par, and Par is barred from enforcing the terms of the license agreement, including the provision by which Concordia agreed not to market an authorized generic version of Kapvay. In fact, after Concordia learned of the FTC's investigation, Concordia released an authorized version of Kapvay in December of 2014. The consent orders also bar Concordia and Par from entering into similar agreements in the future and require both companies to provide notice to the FTC before entering into agreements regarding authorized generic products for twenty years. The consent orders are designed to promote competition in the generic market which in turn results in lower prices for consumers.

Manufacturers and marketers of brand name and generic pharmaceuticals should carefully consider the antitrust implications of patent-related agreements that could have the effect of limiting competition. In order to avoid costly government investigations and antitrust lawsuits, companies should consider engaging outside antitrust and intellectual property counsel to advise them on the potential implications of these agreements beginning in the early stages of the process.

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