Axinn Obtains Summary Judgment Victory Against FDA

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PRACTICE AREAS

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Intellectual Property

Washington, D.C.

A team of attorneys from Axinn successfully obtained summary judgment on behalf of Watson Laboratories, Inc. in litigation against the U.S. Food and Drug Administration in the U.S. District Court for the District of Columbia. The court's ruling, which is under seal, includes an order that paves the way for the company to bring its generic diabetes drug to market. Axinn's team was comprised of partners Chad A. Landmon, Chair of the firm's FDA Practice Group, and Mark D. Alexander.

The case involved a dispute over the 180-day "first-to-file" marketing exclusivity for generic versions of the multi-billion dollar product Actos® (pioglitazone hydrochloride). FDA had denied exclusivity to Watson in August 2012, instead approving one of Watson's competitors. In the summary judgment motion, Axinn argued that FDA's decision should be reversed and that Watson should be entitled to share the marketing exclusivity period.

Today, Judge Amy Berman Jackson issued an order granting Watson Laboratories' Motion for Summary Judgment, and ordered that the FDA "approve Watson Laboratories' ANDA for generic pioglitazone effective immediately so that Watson may participate in what remains of the shared exclusivity period previously awarded to other generic manufacturers of the drug."