

Axinn Represents Purepac Pharmaceutical Company in Metformin Launch

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ATTORNEYS

Keeley, Michael

Landmon, Chad

Veltrop, James

PRACTICE AREAS

Intellectual Property

Axinn represented Purepac Pharmaceutical Company in connection with its launch of various products containing the active ingredient metformin. The firm provided patent and FDA advice and also represented the company in two cases involving exclusivity disputes under the Hatch-Waxman Act. In one case, Axinn lawyers successfully obtained a temporary restraining order from the U.S. District Court for the District of Columbia against the Food & Drug Administration's award of generic marketing exclusivity relating to metformin hydrochloride extended-release tablets, 500 mg, currently marketed by Bristol-Myers Squibb Company under the trade name Glucophage® XR. A hearing on Purepac's motion for preliminary injunction was held on November 12, 2003, at which Axinn argued that FDA's actions were arbitrary and capricious in light of the statutory mandates set forth in the Hatch-Waxman Amendments and FDA's regulatory scheme. Purepac successfully negotiated a settlement of the case shortly thereafter.