

Axinn Successful In Protecting FDA Approval for Client Endo Pharmaceuticals Inc.

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ATTORNEYS

Hedemann, Thomas

Landmon, Chad

PRACTICE AREAS

Intellectual Property

Axinn, on behalf of client Endo Pharmaceuticals Inc., successfully intervened on the side of the U.S. Food and Drug Administration to oppose a motion for temporary restraining order brought by Ranbaxy Laboratories, Ltd. Ranbaxy had sought an order reversing FDA's approval of Endo's generic version of Hoffmann-La Roche, Inc.'s Valcyte® (Valganciclovir Tablets USP, 450 mg). FDA had recently decided to revoke tentative approval of Ranbaxy's valganciclovir product and determined that Ranbaxy had forfeited its generic marketing exclusivity rights.

Working quickly over the course of just a few days, Axinn attorneys Chad Landmon and Thomas Hedemann filed intervention papers and an opposition brief in the U.S. District Court for the District of Columbia. At the hearing on the motion, Chad Landmon argued in front of Judge Beryl Howell on behalf of Endo. Judge Howell denied Ranbaxy's motion, finding that the company failed to show that it would suffer irreparable harm absent the requested relief, and that FDA acted within its authority to revoke tentative approval of Ranbaxy's product and subsequently approve Endo's product.