axinn

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

NEWS | 1 MIN READ

November 19, 2014

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 filed intervention papers and an opposition brief in the U.S. District Court for the District of Columbia. 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.

Related People



Thomas K. Hedemann

Related Services

Intellectual Property

To subscribe to our publications, click here.

Featured Insights

- American Bar Association 2025 Asia-Pacific Conference
 SPEAKING ENGAGEMENT ANTITRUST
- NBA Commercial Law Section 38th Annual Corporate Counsel Conference SPONSORSHIP ANTITRUST
- GCR Live: Law Leaders Global 2025
 SPEAKING ENGAGEMENT ANTITRUST
- The 32nd Annual Marketing Partner Forum
 EVENT
- SABA North America Corporate Counsel Retreat 2025
 SPONSORSHIP ANTITRUST
- Axinn Antitrust Insight: FTC Announces Revised HSR Thresholds for 2025
 CLIENT ALERTS ANTITRUST
- Four Axinn Thought Leadership Pieces Nominated for the Antitrust Writing Awards
 AWARDS & RECOGNITIONS
 ANTITRUST
- Merger Remedies Back in Vogue Under Trump
 MEDIA MENTIONS ANTITRUST
- Three Takeaways from the Initial Determination at the ITC Regarding Standard Essential Patents in the 1380 Investigation

AXINN VIEWPOINTS INTELLECTUAL PROPERTY

 A POSA's Motivation Is Not Required To Be the Same as the Inventor's in Evaluating Obviousness 	
AXINN VIEWPOINTS	INTELLECTUAL PROPERTY
© 2	2025 Axinn, Veltrop & Harkrider LLP. All Rights Reserved