

## Bartlit Beck Obtains Immediate Relief For Bayer In Lanham Act False Generic Drug Advertising Case

*June 2010*

Peter Bensinger, Jr., Adam Mortara, Rob Addy, and Matthew Ford represent Bayer in a Lanham Act false advertising and patent infringement case arising out of Teva's launch of a generic version of Bayer's YAZ® oral contraceptive and product literature claiming that Teva's generic contains Bayer's patented betadex clathrate formulation. Saul Perloff of Fulbright & Jaworski LLP is co-counsel for Bayer.

Bayer moved for a temporary restraining order on June 15, 2010. In a June 16, 2010 proceeding before Judge Virginia Kendall in US Federal Court in the Northern District of Illinois, Teva Pharmaceuticals USA Inc. admitted that the Physician Prescribing Information included with packages of its oral contraceptive Gianvi™, falsely claimed that the ethinyl estradiol in the product was stabilized by Bayer's patented "betadex as a clathrate" formulation, and in fact, that Gianvi does not have Bayer's patented stabilization formulation. Gianvi is Teva's product and is sold as a generic version of Bayer HealthCare's leading oral contraceptive YAZ® (drospirenone & ethinyl estradiol).

Adam Mortara argued for the temporary restraining order on behalf of Bayer.

In response to Bayer's motion for a temporary restraining order and at the end of the hearing before Judge Kendall on the motion, Teva agreed to correct the false label by sending weekly e-mail or fax messages to US pharmacists nationwide for a period of three months. The e-mail or fax messages to pharmacists will provide corrected Physician Prescribing Information that removes the false claim that the ethinyl estradiol in Gianvi is stabilized by betadex as a clathrate and calls the pharmacist's attention to this corrective label change.

Teva also agreed not to ship any additional Gianvi product containing promotional materials, package inserts or any other material falsely claiming that the ethinyl estradiol in Teva's Gianvi is stabilized by betadex as a clathrate. Teva reported that it has already provided the US Food and Drug Administration (FDA) with corrected Physician Prescribing Information for Gianvi and that it has corrected the Gianvi label information on the Teva USA website.

Finally, Teva agreed to send, by e-mail or fax, the corrected Physician Prescribing Information to all known wholesalers, distributors and chain retailers that received Gianvi, and direct them to the label change.

As a result of Teva's agreement to take measures Bayer requested in its emergency motion, the Court denied Bayer's motion for a temporary restraining order without prejudice as moot. Teva was ordered by Judge Kendall to file a compliance report on its progress on these actions by 5:00 pm on Friday, June 18, 2010.

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