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NEWS FROM AV&H

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AV&H Secures Significant Victory for Purepac Pharmaceutical Company in Purepac Pharmaceutical Co. v. Thompson, No. 1:03CV02210 (TPJ) (D.D.C. Oct. 29, 2003)

On behalf of Purepac Pharmaceutical Company, a subsidiary of Alpharma Inc., AV&H lawyers obtained a significant victory relating to Purepac's attempt to market generic metformin hydrochloride extended-release tablets, 500 mg ("metformin ER"), currently marketed by Bristol-Myers Squibb Company under the trade name Glucophage® XR. On October 29, 2003, AV&H 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 ER to IVAX Pharmaceuticals, Inc. ("Ivax"). Based on AV&H's argument 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, Judge Thomas Penfield Jackson entered the TRO, delaying the effective date of FDA's approval of Ivax's Abbreviated New Drug Application ("ANDA") and prohibiting FDA from granting final approval to any other generic company until a hearing was held on Purepac's motion for a preliminary injunction.

Following the entry of the TRO, AV&H submitted extensive briefs in support of Purepac's preliminary injunction motion, arguing that FDA's October 28, 2003 award of the 180-day generic marketing exclusivity to Ivax was arbitrary, capricious and inconsistent with the statutory and regulatory scheme. A hearing was held on the preliminary injunction motion on November 12, 2003, at which AV&H presented arguments regarding the nature of FDA's action. Following the hearing, AV&H submitted additional briefs in response to an FDA affidavit regarding the status of Purepac's ANDA and in response to a surreply submitted by Ivax, which raised issues regarding the policy implications of FDA's decision.

On the eve of a decision by Judge Jackson, the parties entered into a settlement agreement, securing a significant opportunity for Purepac. Under the agreement, Ivax and Purepac will share profits on an approximately equal basis on all sales during the 180-day exclusivity period.

Central to this case were the provisions of the Hatch-Waxman Amendments, which provide that the first generic pharmaceutical company to file an ANDA or an ANDA amendment with FDA asserting that the brand name drug company's patent is either invalid or not infringed (a so-called "Paragraph IV certification") is entitled to a 180-day period as the exclusive generic on the market. With respect to metformin ER, Purepac was the first generic company to file its Paragraph IV certification, which was submitted in an amended ANDA, and was the first company to provide notice to the patent holder regarding such certification pursuant to statutory and regulatory provisions. Purepac argued that a two-day delay in providing notice should not delay the effective date of the filing of its Paragraph IV certification.

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