

No Tentative Approval From FDA Is Required To Permit Generic Drug Manufacturer To Possess Antitrust Standing Against Patent Owner.

In *In re: Metoprolol Succinate Antitrust Litigation*, 2010 U.S. Dist. LEXIS 36303 (D.Del. April 13, 2010), Chief Judge Sleet held that the failure of a generic drug manufacturer to obtain tentative approval during the statutory 30 month stay did not defeat antitrust standing. By so holding, Chief Judge Sleet disagreed with cases from the District of Massachusetts, the Southern District of Florida and the Eastern District of New York.

AstraZeneca further challenged antitrust standing on the grounds that there was no showing that the generic drug companies actually diverted resources from the FDA approval process as a result of AstraZeneca's lawsuits. Chief Judge Sleet held that this inquiry was too factual to be resolved on a motion to dismiss.