Favorable Ruling for Gatifloxacin Patent Dispute in Canada

Kyorin Pharmaceutical Co., Ltd. (President: Ikuo Ogihara) ("Kyorin") announces that on October 28, 2005, an Ottawa, Canada federal court issued an order of prohibition in an action brought against Novopharm Limited, the wholly owned Canadian subsidiary of generic maker Teva Pharmaceutical Industries Limited, and the Canadian Minister of Health. The order is based on Kyorin's Canadian patent, 1,340,316 (the "316 patent"), covering the broad spectrum antibacterial agent known generically as gatifloxacin (Japan trade name: GATIFLO[®]; Canada trade name: TEQUIN[®]). TEQUIN® is sold in Canada by Bristol-Myers Squibb Canada Co. ("BMS Canada").

The prohibition order stems from an action, called a prohibition action, filed in May 2004 by Kyorin and BMS Canada against Novopharm and the Canadian Minister of Health. Kyorin and BMS Canada filed the prohibition action in response to a Notice of Allegation ("NOA") received from Novopharm in April 2004. Novopharm's NOA indicated that it had filed an abbreviated new drug submission ("ANDS") for gatifloxacin, and that it sought to market that generic version before the expiration of Kyorin's '316 patent. Novopharm's NOA further alleged that the '316 patent was invalid.

The court's order of prohibition prevents the Minister of Health from issuing final approval, referred to as a notice of compliance, of Novopharm's ANDS until the expiration of the '316 patent in 2016.