

February 2012: Life Science Litigation Update

Federal Circuit Vacates Preliminary Injunction in Pharmaceutical Case

In *Warner Chilcott Labs. Ireland Ltd. v. Mylan Pharms. Inc.*, No. 2011-1611 (Fed. Cir. Dec. 12, 2011), the Federal Circuit vacated a preliminary injunction entered by the U.S. District Court for the District of New Jersey to prevent Mylan from launching a generic version of 150 mg Doryx, which is the branded name for the doxycycline hyclate delayed-release tablets sold by plaintiffs Warner Chilcott and Mayne Pharma International (the "Plaintiffs"). Doryx is covered by United States Patent No. 6,958,161, which discloses a modified release coated form of doxycycline.

Upon approval of Mylan's ANDA, the Plaintiffs sued for infringement within the period prescribed by the Hatch-Waxman Act. Mylan responded that the '161 patent was not infringed, and was invalid and unenforceable. The question of infringement turned on whether Mylan's generic Doryx product included a "stabilizing coat" as required by the only asserted claim. In addition to pursuing an infringement claim against Mylan, Plaintiffs also moved for a preliminary injunction shortly before the FDA's thirty-month stay of final approval was set to expire. In particular, Plaintiffs argued that (1) they were likely to succeed in proving that Mylan's product infringed the '161 patent by incorporating a "stabilizing coat" in its capsule formulation; (2) they would suffer irreparable harm absent an injunction; (3) the balance of hardships favored Plaintiffs; and (4) public policy interests demanded that an injunction be entered. The district court agreed.

On appeal, Mylan challenged the district court's decision, arguing that the district court abused its discretion by entering a preliminary injunction preventing the FDA from granting final marketing approval to Mylan's generic Doryx product. The Federal Circuit ultimately agreed with Mylan, finding that the district court abused its discretion in two ways. Relying predominantly on Third Circuit authority, the Federal Circuit first determined that the district court failed to hold an evidentiary hearing despite acknowledging that the decision turned on disputed factual issues. At the preliminary injunction hearing, the court's primary focus was on the question of whether Mylan's ANDA product incorporated a "stabilizing coat"—i.e., whether Plaintiffs were likely to succeed on the merits of their infringement claim. Although recognizing that this question turned on a battle of the experts, the court refused to hold an evidentiary hearing or hear live testimony despite Mylan's request. Second, the district court failed to weigh any evidence or make any findings with respect to Mylan's claim that the '161 patent was invalid and unenforceable. Despite vacating the preliminary injunction, the Federal Circuit indicated that the district court may consider entering a temporary restraining order until a consolidated preliminary injunction hearing and bench trial on the merits can be held, assuming such a hearing can be held within the timeframe mandated by the Federal Rules of Civil Procedure.