Ranbaxy Pharmaceuticals Inc. (RPI), a manufacturer of generic pharmaceuticals, announced on February 1, 2007, that it received FDA approval to market generic valacyclovir hydrochloride tablets. Unlike other companies that have received FDA approval for generic valacyclovir formulations, though, Ranbaxy has issued a direct challenge to GSK's patent for its valacyclovir HCI drug, Valtrex®,which does not expire until June 2009.

When RPI, a wholly owned subsidiary of India-based Ranbaxy Laboratories Limited, filed its abbreviated new drug application (ANDA) with the FDA, it included a "paragraph IV certification" which calls into question the validity of a patent or patents. In response, GSK filed a patent infringement lawsuit against Ranbaxy in May 2003 in the District Court of New Jersey.

With the recent FDA approval, GSK issued an update to the lawsuit. In a statement, GSK announced, "Under the terms of an agreement between the companies, previously approved by the court, if GSK applies for such an injunction within 45 days, Ranbaxy will not launch its product until the court either rules on the preliminary injunction or decides the pending court case." No trial date has been set as of yet.

While the two companies may be at odds over the patent issue in the U.S., they recently extended their ongoing research and development collaboration. In 2003, GSK and Ranbaxy Laboratories Limited entered into a drug discovery and product development deal with Ranbaxy responsible for early stage chemical tests to take drug leads to the candidate selection stage. Under the terms of the new agreement, Ranbaxy will move on to phase II clincal trials while GSK will take products through further stages of clinical development and the regulatory approval process.