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Extension of Regulatory Approval Stay Helps Relieve Hatch-Waxman Time Pressure Caused by COVID-19

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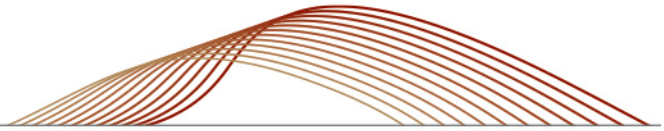
In response to the COVID-19 pandemic, courts throughout the United States have restricted access to chambers and postponed in-person proceedings. As the pandemic deepened, Paul Hastings' litigation practice created a summary of the respective court orders regarding closings, cancellations, and restrictions, which may be found here. These restrictions have created unique time pressures in Hatch-Waxman Act cases because of the need to resolve the case before the end of the automatic stay of FDA approval of the accused generic product. In this alert, we discuss a solution to the problem recently achieved in one of the Paul Hastings life science patent practice cases, which could serve as a model for others.

The Hatch-Waxman Act, also known as the Drug Price Competition and Patent Term Restoration Act of 1984, provides a legal framework for generic drug products to enter the United States market. Under this framework, companies seeking to sell generic versions of FDA-approved drugs can submit an abbreviated new drug application ("ANDA"), which uses information in an innovator's approved new drug application ("NDA") to seek FDA approval under section 505(j) of the Federal Food, Drug, and Cosmetic Act. To aid in this endeavor, all approved NDAs are listed in the FDA's "*Approved Drug Products with Therapeutic Equivalence Evaluations*" (referred to as the "Orange Book"), along with the patents that cover the drugs that are the subjects of these NDAs. If an ANDA is filed on a drug with unexpired Orange Book-listed patents, the ANDA filer must include a certification regarding whether any such patent is invalid or will not be infringed by the ANDA product. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). If the ANDA filer includes such a certification (called a "paragraph IV certification"), it must provide written notice to the patent and NDA holder. *See id.* § 355(j)(2)(B)(iii).

If the patent and NDA holder file a lawsuit within 45 days of receiving such notice, then an automatic 30-month stay of the ANDA's regulatory approval is triggered under the statute. *See id.* § 355(j)(5)(B)(iii). To the extent such a paragraph IV certification is filed during the final year of the five-year New Chemical Entity exclusivity, the statutory stay is extended to seven and one-half years from the date of the NDA approval. *See id.* § 355(j)(5)(F)(ii). During such regulatory stays (either 30 months or 7.5 years), the FDA may not approve the generic's pending ANDA, which prevents an ANDA filer from launching its generic product "at risk" and potentially subjecting it to damages. These regulatory stays also avoid the need for patent and NDA holders to move for a preliminary injunction, and provide courts the time to consider the parties' arguments. These regulatory stays are such a



critical component of litigations under the Hatch-Waxman Act that many jurisdictions require notice of their expiration at the start of the action. *See, e.g.*, D.N.J. L. Pat. R. 2.1(a)(6). Accordingly, the delay of Hatch-Waxman litigations as a result of the COVID-19 pandemic could result in courts being inundated with emergency preliminary injunction briefings as the regulatory stays expire.

A team of Paul Hastings' attorneys litigating several Orange Book-listed patents in the District of New Jersey were facing just this scenario. At the beginning of year, the team identified the potential shuttering of court proceedings, including the scheduled May 2020 trial (at that time, less than six months away). The group continued to prepare for trial, but kept a close eye on all COVID-19 developments. The team's focus at that time was monitoring travel restrictions and safety recommendations since trial was expected to involve clients and witnesses needing to travel from across the globe, including Japan and Europe.

As March approached and the COVID-19 situation worsened, the Paul Hastings' team reevaluated its strategy relating to the May trial and devised a plan to ensure the safety of its clients and witnesses, as well as alleviate pressure on the court amid the COVID-19 turmoil. The focus shifted to extending the fast-approaching end of the stay of regulatory approval, which was set to expire on September 29, 2020. The Paul Hastings team spearheaded negotiations with opposing counsel to extend the regulatory stay in a way that was agreeable to both parties while providing the court with ample time to hear and decide the matter, which also avoided the need for any preliminary injunction proceeding. During the March 31, 2020 Final Pretrial Conference, the parties conveyed their proposal to the presiding judge, who greatly appreciated their work to resolve the issue before court intervention was required. The parties thereafter formally notified the court of their agreement, which allowed for postponement of the May 2020 trial by extending the regulatory stay for 120 days from the conclusion of the rescheduled trial date, to be set at the court's convenience. The court signed the order on April 24, 2020, which is available here. Solutions for these types of potential issues are not only critical during this time of quarantine, but may continue to be important for some time after district courts reopen given their need to prioritize criminal cases that have been delayed.

COVID-19 has caused many uncertainties for clients, but proactive thinking from litigators can help limit the unknowns. The actions by the Paul Hastings' litigation team can serve as a model for other litigants to aid the courts in difficult times and help ease client concerns.

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If you have any questions concerning these developing issues, please do not hesitate to contact the following Paul Hastings New York lawyer:

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