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# Client Alert

## Federal Circuit Affirms Extension of The 30 Month Hatch-Waxman Stay Preventing FDA Approval of Generic Version of Evista

**February 27, 2009**

For the first time, the Federal Circuit has affirmed the extension of a thirty month stay under the Drug Price Competition and Patent Term Restoration Act (known as the "Hatch-Waxman Act"). The U. S. District Court for the Southern District of Indiana extended the stay because the generic company recast its product, disclosing new samples only eight months before trial was to commence and produced documents after the discovery cut-off. But a vigorous dissent claims that what the majority had done is to "effectively eliminate the statutorily required finding."

At issue *in Eli Lilly & Co. v. Teva Pharms. United States, Inc* ., 2009 U.S. App. LEXIS 3526 (Fed. Cir. 2009) was when, under the Hatch-Waxman Act, a trial court has the discretion to extend the thirty month stay that prevents the FDA from approving a generic drug for distribution while the branded and generic companies litigate any patent infringement issues.

Chief Judge Paul R. Michel and Judge Randall R. Rader held that District Judge Sarah Evans Barker had acted within her discretion in granting the extension, emphasizing that "Teva altered its generic [Evista] tablets late in the litigation."

Judge Sharon Prost dissented, arguing that the thirty month stay period was "a hard-won compromise" that "ceases to have meaning when district courts are able to modify the stay without articulating why the narrow circumstances described in the statute are present."

Under the ruling, Teva has seven days to file a petition for panel rehearing or rehearing *en banc*.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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