Reuters

Drug pacts keep some generic off market - FTC

By Peter Kaplan

WASHINGTON (Reuters) - Brand-name drug makers are striking more deals with generic rivals to restrict the introduction of cheaper generic drugs, antitrust authorities said on Monday.

Emboldened by recent victories in court, pharmaceutical companies are using controversial settlements that entail payments to generic rivals which promise to restrict selling competing generic drugs, a Federal Trade Commission official said in a speech on Monday.

"We are seeing far more settlements today that potentially raise competition concerns," FTC Commissioner Jon Leibowitz said in prepared remarks for a Philadelphia business group. Leibowitz's comments came on the same day the FTC released a report on patent settlements among drug companies. The FTC has filed lawsuits in recent years challenging patent settlement agreements between major drugmakers and their generic rivals. In some cases, the FTC contends the settlements stifle competition because drugmakers are paying generics to stay out of the market. Generic drugs are typically cheaper for consumers to buy than brand-name drugs.

Under federal law, drugmakers are allowed to seek U.S. Food and Drug Administration approval for generic versions of brand-name drugs before a drug's patent expires. They must certify that the patent is invalid or will not be infringed by the new generic version. However, in one key decision last year, an appeals court in Atlanta overturned an FTC ruling that said Schering-Plough Corp. had illegally kept cheaper versions of its blood pressure drug K-Dur off the market through patent settlements with generic competitors.

Months later, another federal appeals court upheld a lower court decision throwing out a similar case involving AstraZeneca Plc's cancer drug Tamoxifen. The FTC has petitioned the U.S. Supreme Court to review the Schering-Plough decision. The court has not yet decided if it will review the case. The FTC has monitored drug patent settlements closely since 2004, when Congress passed a law requiring drug companies to notify the FTC about them in advance.

In the report issued on Monday, the FTC found that in fiscal 2005, three of 16 drug patent settlements included payments to the generic drug and restrictions on when it would become available, according to the FTC report. It was the first time since 1999 that drug companies entered in such agreements, the FTC said.

During the past six months, Leibowitz said, at least seven of the 10 settlements reported to the agency included those kinds of provisions.

He cited recent settlements involving Plavix, a drug-thinner blood manufactured by Bristol-Myers Squibb and
Sanofi-Aventis, and Provigil, a sleep disorder drug made by Cephalon Inc. Leibowitz said he offered no opinion on whether those specific "truce" agreements were legal.

But, unlike most other drug patent settlements, the Plavix agreement will require the approval of the FTC because of a consent agreement Bristol-Myers signed to resolve a previous antitrust case with the agency.

Cephalon's general counsel, John Osborn, said company officials "believed in the strength of the underlying patent that was at issue" but decided to settle these cases to give the company and investors "certainty" about the future. Osborn said the settlements set out "legitimate business relationships" with the generic manufacturers. Under the terms of the deals, generics get to enter the market with competing drugs in 2012, three years before Cephalon's market exclusivity expires.