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Price Fixing

Senators Request Overdue Pay-for-Delay Reports From FTC

Sens. Amy Klobuchar (D-Minn.) and Chuck Grassley (R-Iowa) are asking the Federal Trade Commission to release its reports on “pay-for-delay” agreements that postpone generic drugs going to market.

Klobuchar and Grassley have previously requested these reports when they haven’t been released on time. Although the agency is short-staffed, the request is a “signal to the agency that we remain very interested in this topic,” an aide to Klobuchar told Bloomberg BNA.

Klobuchar and Grassley sent the most recent letter July 13 to FTC Acting Chairman Maureen Ohlhausen asking when the fiscal 2015 and fiscal 2016 reports will be released. Klobuchar and Grassley also requested the projected date of release for the fiscal 2017 report.

Pay-for-delay settlements are legal agreements between a brand-name drug manufacturer and a generic competitor in which the generic competitor agrees to wait to market a generic drug, typically in exchange for a payment from the brand-name manufacturer. Also known as “reverse payments,” these settlements are used by brand-name drug manufacturers to manage competition. When a brand-name drug patent expires, the manufacturers use this technique to prevent prices falling as generic manufacturers sell their product.

In *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 570 U.S. 756 (2013), the Supreme Court held that pay-for-delay agreements may be found unlawful under antitrust law.

Help Congress Understand Grassley and Klobuchar’s letter said the FTC reports on pay-for-delay activity “will help Congress understand whether the court’s decision has altered the behavior of drug manufacturers and what legislative reforms are currently needed.”

The Supreme Court left it to the lower courts to determine what types of reverse payment devices are lawful and what devices are not, which has led to difficulties in interpreting the law. The difficulties have resulted in inconsistent rulings.

Klobuchar and Grassley said pay-for-delay agreements “deny consumers access to more affordable alternatives to brand medications.”

“We expect the reports to show these deals are still going on,” said the aide to Klobuchar.

Teeing Up Interest Klobuchar and Grassley sponsored legislation to make such deals illegal. They introduced the Preserve Access to Affordable Generics Act (S. 124) in January and sponsored similar legislation in the last Congress.

The Senate Judiciary Committee’s antitrust subcommittee, of which Klobuchar is the ranking member and Grassley is a member, held a hearing on the bill in the last Congress. No action has been taken on the current bill since its introduction in the Senate.

We hope the “reports will help build interest in the legislation,” said the aide to Klobuchar.

The FTC has released annual reports on agreements between brand and generic drug manufacturers since 2004. The report for fiscal 2014 was released in January 2016, and no reports on the subject have been released since then.

Klobuchar and Grassley previously sent a letter to the FTC in October 2014 requesting the annual reports on these agreements for fiscal 2013 and fiscal 2014.

A spokeswoman for the FTC confirmed the agency received the letter.

By SHIRA STEIN

To contact the reporter on this story: Shira Stein in Washington at sstein@bna.com

To contact the editor on this story: Fawn Johnson in Washington at fjohnson@bna.com