Congress of the United States

Washington, D.C. 20515

May 17, 2006

Ms. Kathleen Jaeger
President and CEO
Generic Pharmaceutical Association
2300 Clarendon Boulevard
Suite 400
Arlington, VA 22201

Dear Ms. Jaeger,

We are writing today regarding the resurgence in patent settlement agreements in which a generic firm agrees to keep its drug off the market in exchange for a payment from the brand-name pharmaceutical company. We are deeply concerned that these kinds of settlements may be improperly delaying consumer access to generic medications, and therefore subverting the intention of the 1984 Hatch-Waxman law. We urge you to take a strong and public stance against this practice, which exploits a law intended to save consumers money, and enriches only the companies involved.

As you know, these settlement agreements arise in the context of patent infringement lawsuits filed against generic firms seeking to market generic versions of brand-name drugs. In the interest of promptly concluding the dispute, the parties often agree to a patent settlement setting forth terms and conditions by which the generic drug may be marketed. In many cases, patent settlement agreements can provide great benefit not only for the parties involved, by allowing them to avoid protracted litigation, but also for consumers, by speeding the entry of generic drugs that might otherwise have been deferred by the litigation.

However, beginning in the late 1990's, these settlement agreements began to include agreements by the generic firms to stay off the market in exchange for payments from the brand-name firms. In 1999, the FTC challenged several such agreements as being anti-competitive and, shortly thereafter, the use of these agreements plummeted. In the years for which the FTC has data between 2000 and 2004, legitimate patent settlements continued, but none contained payments to the generic company or restrictions on the generic firm's ability to market its product.[1] It is thus clear that patent disputes can be settled without such anti-competitive agreements.

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[1] FTC, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003- Summary of Agreements Filed in FY 2005 – A Report by the Bureau of Competition*, at 4 (online at: http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf). FTC's data reflects the six settlements entered in 2000 and 2001 and the fourteen settlements entered in 2004.

In 2005, however, two appellate court decisions reversed FTC's long-standing position, and upheld settlements that included such reverse payments.[2] Unfortunately, these court decisions appear to have prompted a resurgence in these potentially anti-competitive settlement agreements. FTC recently released a report comparing the pharmaceutical patent agreements entered into 2005 to those entered into between 2000 and 2004. FTC found that, in the six months following the March 2005 court decisions, there were three settlement agreements in which the generic received compensation and agreed to a restriction on its ability to market the product.[3] Additionally, although the data is not yet complete for 2006, more than two-thirds of the approximately ten settlement agreements between brands and generics included a payment from the brand in exchange for a promise by the generic company to delay generic entry into the market.[4]

GPhA—along with the entire generic drug industry—has always shown great leadership in the struggle to ensure that Americans have access to affordable drugs. We are dismayed that generic firms are not only participating in patent settlements that subvert the objectives of the Hatch-Waxman law, but that GPhA has failed to show any effective leadership on this issue. We urge you to immediately express your strong opposition to these settlement agreements that serve only to benefit the drug companies involved while depriving consumers of the great cost-savings of generic drugs.

Sincerely,

Henry A. Waxman
Member of Congress

Charles E. Schumer
United States Senator

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[2] In 2003, FTC challenged an agreement in which Schering-Plough paid Upshur in exchange for deferring marketing of its generic version of K-Dur. *Schering-Plough Corp. v. FTC,* 402 F.3d 1056 (11th Cir. 2005). Similarly, FTC recently challenged another settlement agreement in which Zeneca paid Barr $21 million to keep its generic off the market until patent expiration. *In re Tamoxifen Citrate Antitrust Litig.*, 429 F. 3d 370 (2d. Cir. 2005).

[3] FTC, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, at 4 (online at: http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf).

[4] Remarks by Jon Leibowitz, Commissioner, Federal Trade Commision, *Exclusion Payments to Settle PharmaceuticalPatent Cases: They're B-a-a-a-ck!* April 24, 2006 (online at: http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf). Data covers agreements between October 1, 2005 and March 31, 2006.