U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

February 12, 2008

Senator Jon Kyl
United States Senate
Washington, D.C. 20510

Dear Senator Kyl:

This responds to your request for the Department's views regarding the competitive implications of S. 316, the "Preserve Access to Affordable Generics Act." S. 316 addresses the issue of reverse payments associated with the settlement or resolution of an infringement lawsuit in the context of the Hatch-Waxman Act. The bill would make it a per se violation of the antitrust laws to be a party to an agreement in which an Abbreviated New Drug Application (ANDA) filer receives value and agrees not to research, develop, manufacture, market, or sell the ANDA product for any period of time. The Department believes that the bill addresses a serious competition issue, but, for the reasons discussed below, the Department has concerns with this bill as drafted.

As an initial matter, there is the potential for such settlements to be anticompetitive. For example, if the potential losses in profits due to increased competition from entry by the ANDA filer are large, the ANDA filer may be persuaded to drop a strong claim of patent invalidity or non-infringement in return for significant payments. As described below, however, settlements between an ANDA flier and the patent holder also can benefit consumer welfare. Accordingly, the Department of Justice does not believe per se liability under the antitrust laws is the appropriate standard. Per se liability generally is reserved for only those agreements that unequivocally have an anticompetitive effect, while a rule of reason analysis is better suited to instances when the economic impact of the agreement is less certain. In this context, per se illegality could increase investment risk and litigation costs to all parties. These factors run the risk of deterring generic challenges to patents, delaying entry of competition from generic drugs, and undermining incentives to create new and better drug treatments or studying additional uses for existing drugs.

The United States has a strong policy of encouraging settlement of litigation. A settlement reduces the time and expense of litigation, which can be quite substantial. Further, it reduces the uncertainty associated with the pending litigation. A settlement can thereby free up management time and resources and reduce risk, enabling a company to focus on developing new and better products.

The Hatch-Waxman Act context presents a distinct set of circumstances, but settlements in this context nonetheless implicate the same considerations. While drug companies may be able to assert patent rights to prevent the entry of generic equivalents, the Hatch-Waxman Act

creates a structure designed to encourage generic drug makers to challenge these patent rights by asserting either that the relevant patents are not valid or that the generic version would not infringe the patents. Among other things, the Hatch-Waxman Act provides an opportunity for the generic company and the patent holder to litigate those issues prior to the generic's launch of a potentially infringing product. Thus, unlike most patent litigation in which the patent holder has a claim for damages, the patent holder in the Hatch-Waxman context typically has no claim for damages because the generic company has not yet launched a product.

In any patent litigation, the principle means available to the patent holder to induce the generic company to settle the litigation is to offer something of value. If the patent holder has a damages claim for infringement, it can offer to reduce or waive its damages. However, in the Hatch-Waxman context the patent holder typically has no damages claim, so its only means of offering value to induce a settlement is to offer to transfer something of value, such as cash or other assets. Under S. 316, the only value that a patent holder could offer to settle a patent infringement claim would be "the right to market the ANDA product prior to the expiration of the patent" at issue (i.e., waiving its patent rights in whole or in part). The per se liability under S. 316 eliminates any other transfer of value if the settlement also includes a provision requiring the generic company to respect for any period of time the patent holder's right to exclude under the patent. The net result may be to reduce the likelihood of potentially beneficial settlements and to increase the risk that a generic company would need to litigate a case to judgment (and through an appeal in many instances). Patent holders would face greater disincentives to investing in research and development of new and better treatments if they had to litigate every challenge to a judgment and through an appeal. Further, such litigation can take many years to complete and will divert the time, attention and resources of both parties during that time.

Settlement should not serve as a vehicle to enable patent holders to preserve or expand invalid or non-infringed patents by dividing anticompetitive profits with settling challengers. However, the public policy favoring settlements, and the statutory right of patentees to exclude competition within the scope of their patents, would potentially be frustrated by a rule that subjected patent settlements involving reverse payments to automatic or near-automatic invalidation. These competing considerations suggest that an appropriate legal standard should take into account the relative likelihood of success of the parties' claims and the potential benefits of a settlement in a given situation. It is important that parties maintain the ability to settle, and that the law permit flexibility for settlement negotiations to capture efficient agreements that are motivated by legitimate business objectives rather than anticompetitive goals.

Finally, we note that subsection 4(a) of the bill appears to contain a typographical error. We believe that the intended reference to the United States Code should be "21 U.S.C. § 355 note" (rather than section "3155").

Thank you for the opportunity to present our views. Please do not hesitate to call upon us if we may be of additional assistance. The Office of Management and Budget has advised us

that, from the perspective of the Administration's program, there is no objection to submission of this letter.

Sincerely,

Brian A. Benczkowski
Principal Deputy Assistant Attorney General