



July 19, 2011

The Honorable Patrick Leahy  
Chairman,  
Senate Judiciary Committee  
244 Dirksen Senate Office Bldg  
Washington, DC 20510

The Honorable Chuck Grassley  
Ranking Member,  
Senate Judiciary Committee  
152 Dirksen Senate Office Bldg  
Washington, DC 20510

**Re: IPO Opposes S. 27, the “Preserve Access to Affordable Generics Act”**

Dear Chairman Leahy and Ranking Member Grassley:

Intellectual Property Owners Association (“IPO”) writes to express its opposition to S. 27, “Preserve Access to Affordable Generics Act” and to urge you to vote against S. 27 in the Senate Judiciary Committee.

IPO is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in intellectual property rights. IPO’s membership includes more than 200 companies and more than 12,000 individuals involved in the association either through their companies or as inventor, author, executive, or law firm members.

S. 27 would amend the Federal Trade Commission Act (15 U.S.C. § 44 *et seq.*) to add a new Section 28 and would create a presumption of anti-competition and illegality of so-called “reverse payment” settlements of pharmaceutical patent litigation. Such settlements are defined broadly in the legislation as any settlement in which an innovator pharmaceutical company gives something of value to a generic litigant and the generic litigant agrees not to research, develop, manufacture, market or sell a product under its Abbreviated New Drug Application (“ANDA”) for a period of time. This presumption of anti-competition and illegality could be rebutted only if the parties to the agreement demonstrate by clear and convincing evidence that the procompetitive effects of the agreement outweigh the anticompetitive effects of the agreement. S.27 would also increase the penalties for violation the new Section 28, authorizing a civil penalty up to three times the value received by any party that is attributable to the violation.

IPO does not believe that consumers are harmed by “reverse payment” settlements. In many instances, consumers benefit by such settlements, which provide for certain generic products to launch before the expiration of the litigated patent. Settlement agreements may promote competition because they may provide market entry of a generic before the generic company would otherwise have been able to enter, that is, at the expiration of a valid and enforceable patent. Reverse payment settlements also supplement the generic pharmaceutical industry, allowing for potentially lower generic drug prices.

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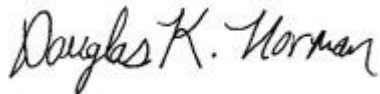
By imposing a presumption of anti-competition and illegality, S. 27 undermines and devalues pharmaceutical patents by imposing a presumption that any settlement involving a payment to the generic applicant is to protect an undeserved pharmaceutical patent.

This legislation would upset the careful balance of the Hatch-Waxman Act which provides an expedited approval pathway for generic pharmaceutical manufacturers without undermining the innovator pharmaceutical developer's incentives to continue investment and development of life-saving medicines. Our strong patent system has encouraged capital investment by innovator companies in costly and risky laboratory research and clinical trials to develop new pharmaceutical products that extend life and alleviate human suffering. A collateral effect of this continuous cycle of innovation is the eventual availability of a greater number of generic products. However, without the protection of a robust patent system, pharmaceutical products can be easily copied with little investment, interrupting the cycle of new investment in research and clinical trials for the development of new drugs.

IPO believes that current antitrust laws are adequate to challenge settlement agreements that are truly anticompetitive. The FTC already has broad powers to monitor Hatch-Waxman settlement agreements and enforce its powers when warranted. The courts also have the power under existing antitrust law to hold the settlement unlawful when warranted.

For these reasons, IPO is strongly opposed to S. 27 and urges you to vote against S. 27 in the Senate Judiciary Committee. Please let us know if you have any questions. We stand ready to assist in any way we can.

Sincerely,



Douglas K. Norman  
President

cc: Senate Judiciary Committee