

September 11, 2002

The Honorable Charles Schumer
U.S. Senate
Washington, DC 20510

VIA FACSIMILE: 1-202-228-3027

Dear Senator Schumer:

I request that you oppose S. 812, legislation to alter the Hatch-Waxman Act. The bill raises serious concerns for our membership. I urge you to work on a more considered basis on any effort to revise the carefully-balanced Hatch-Waxman system.

I understand that under the reported bill, a patent owner who for any reason fails to initiate litigation against a generic drug applicant within 45 days of receiving notice under the ANDA procedure will be *barred* from enforcing patent rights in *any* forum against either the ANDA applicant or any party that manufactures, uses, sells or offers for sale the approved drug product. In addition, a new drug applicant – who may not even be the patent owner – who fails to list a patent with the FDA within 30 days of approval of a new drug application, or within 30 days of the grant of a patent if that occurs after the NDA is approved, is similarly barred from enforcement of patent rights on the drug against a generic manufacturer. Either of these events will *completely abolish patent rights in new drugs or related technology*.

The legislation also creates new opportunities for generic drug makers to harass biotech companies through unnecessary and pointless litigation. The reported bill would create a private right of action to permit a generic manufacturer to *challenge* these mandatory patent listings. The legislation also would allow generic drug applicants to initiate this litigation regardless of whether our companies or their partners intend to assert their patent rights in the ANDA process.

The proposal would codify fifteen pages of FDA regulations governing “bioequivalence” requirements on *both* new drugs and generics and would legislatively shield the FDA from challenges to its actions in setting approval standards. In essence, the proposed changes would make it impossible for drug manufacturers, whether pioneer or generic, or members of the public, to challenge improper standards enacted by the agency on key approval criteria, or to challenge improper decisions made under valid authority. Moreover, the current regulations include several provisions in which FDA provides *to itself* unfettered discretion to create or define at will *any standard “deemed adequate by FDA.”* This makes an otherwise legitimate challenge to an agency decision virtually impossible to sustain. Shielding the agency from actions to challenge its proper authority simply makes no sense, particularly when the consequences involve potential risks to patients and to public health.

I urge you to oppose S. 812. The implications of the changes being proposed are far reaching and will significantly and adversely impact biotechnology companies. They would severely diminish the incentives of the patent system for our industry to develop newer, safer, easier to administer and more effective drugs that could help patients lead better lives. The changes, simply stated, will not yield better results for patients or the biotechnology industry.

Very truly yours,

Karin A. Duncker
Executive Director
New York Biotechnology Association