

Bingaman-Vitter-Brown-Merkley Fair And Immediate Release of Generic Drugs Act of 2011

(FAIR GENERxICS Act of 2011)

Why is legislation needed?

Prices for brand-name prescription drugs have continued to outpace inflation. For example, in 2008 spending in the US for prescription drugs was \$234.1 billion, nearly 6 times the \$40.3 billion spent in 1990.¹ Generic drugs can be an important source of affordable prescription drugs for many Americans. On average, generic drugs are four times less expensive than name brand drugs.²

Pay-for-delay patent settlements between brand and generic pharmaceutical manufacturers, however, are delaying timely public access to generic drugs, which costs consumers and taxpayers billions of dollars annually. In 2010 the Federal Trade Commission reported 31 such settlements (a 60 percent increase since 2009) and in 2011 FTC reported 28 such settlements.³ Many experts and consumer advocates have called for legislation to address this problem and ensure access to affordable medicines for all Americans.

The Bingaman-Vitter FAIR GENERxICS Act of 2011 addresses the root cause of anti-competitive pay-for-delay settlements between brand and generic pharmaceutical manufacturers: the unintended, structural flaw in the Hatch-Waxman Act that allows “parked” exclusivities to block generic competition. By doing so, the legislation ensures consumers will benefit from full and fair generic competition at the earliest, most appropriate time.

The underlying approach of the legislation is supported by experts and consumer advocates.⁴

Summary

The legislation would prevent “parked exclusivities” from delaying full, fair, and early generic competition by:

- Granting the right to share exclusivity to any generic filer who wins a patent challenge in the district court or is not sued for patent infringement by the brand company; and
- Maximizing the incentive for all generic challengers to fight to bring products to market at the earliest possible time by holding generic settlers to the deferred entry date agreed to in their settlements.

¹ Kaiser Family Foundation “Prescription Drug Trends”. May 2010. Available at: <http://www.kff.org/rxdrugs/upload/3057-08.pdf>

² *Id.* at page 3.

³ See 2010 FTC report at: <http://www.ftc.gov/opa/2011/05/mmreport.shtm> and 2011 report at: <http://www.ftc.gov/os/2011/10/1110mmaagree.pdf>

⁴ See full list of supports at end of this summary. See e.g., Harvard Journal of Law and Technology May 13, 2011. Available at: <http://jolt.law.harvard.edu/digest/patent/patent-settlements-under-hatch-waxman-a-look-at-the-proper-standard-of-antitrust-review-and-a-call-for-a-legislative-response>

- Creating more clarity regarding litigation risk for pioneer drug companies and generic companies by requiring pioneer companies to make a litigation decision within the 45 day window provided for in the Hatch-Waxman Act.

As a result, companies who prevail in their patent challenges and immediately *come to market* may be the *sole beneficiary* of the 180 day exclusivity period. In addition, companies will understand litigation risk before launching generic products.

Background

Brand and generic companies are increasingly blocking the market to generic drugs by exploiting an unintended flaw in the Hatch-Waxman Act (the “Act”). The Act awards a 180-day period of market exclusivity to the first generic company to *submit* an application for product approval to the FDA that includes a challenge to a brand company patent. This exclusivity period provides substantial income to the generic company and is the central incentive for generics to be the “first to file” an application challenging a brand patent with the FDA. However, as currently structured, the Hatch-Waxman Act does not provide sufficient incentive for the first generic filer to begin selling its product at the earliest possible time. The first generic challenger *does not have to win* its patent challenge in exchange for the 180 day exclusivity period; it retains the exclusivity reward even if it settles its patent challenge with the brand company rather than pursuing a court decision (and even if another generic company successfully challenges the disputed patent in court). Indeed, in some instances the first generic challenger may *win a court decision and still settle* with a brand name company in order to avoid further litigation. For the generic company, the paramount goal is guaranteeing retention of the exclusivity, not entering the market at the earliest appropriate time. Settling guarantees access to the exclusivity for the generic challenger but also systematically delays consumer access to the generic. Thus, a reward that was intended to facilitate early consumer access to the generic is being systematically abused to delay generic competition.

Once the first generic challenger settles, *all other generic competitors are blocked from entering the market*. Subsequent generic companies may not enter the market without a favorable appellate court decision upholding their patent challenge (which can take many years) and only after a first generic challenger has exercised any rights to exclusivity. As a result, a generic company that may be ready, willing, and able to come to market may be blocked from entering the market until 180 days after the settling generic enters the market, which could be years after an agreement is reached. For example, if a first filer agrees in a 2011 settlement to delay marketing its product until 2018, no other generic company will be allowed to enter the market until 180 days after the first generic finally enters the market in 2018. The exclusivity period in such settlements is described as having been “parked” by the first filer until the 180-day term begins. Subsequent generic filers, moreover, have no incentive to pursue their patent cases, because if they win, first filers can exercise their exclusivity and subsequent generic filers are not rewarded for the victory – their success benefits their competitors first and foremost.

Consequently, generic manufacturers that were not the first-to-file, but may be ready and able to launch a generic product have no meaningful incentive to do so. Markets that should be fairly open to generic competition thus remain blocked for years longer than was originally envisioned under the Hatch Waxman exclusivity periods – and at enormous cost to consumers, the federal government, and the American health care system.

This legislation has broad support from consumer advocates, the generics industry, and experts including: AARP, Apotex generics manufacturer, Families USA, U.S. PIRG, Consumers Union, Consumer Federation of America, Center for Medicare Advocacy, and the National Legislative Association on Prescription Drug Prices, and Alliance for Retired Americans; Community Catalyst.