The Second Look at Drug Patents Act of 2019

Sponsored by Senator Patty Murray (D-WA) and Senator John Cornyn (R-TX)

The Problem

Families across the country are struggling to afford the treatments they need due to high drug costs. Yet, for years, many brand name drug manufacturers have abused the patent system to maintain an unfair competitive advantage over companies willing to bring lower-cost generic drugs to the market. This conduct contributes significantly to the high price of prescription drugs. Specifically, many manufacturers utilize a process known as "patent evergreening," in which they apply for follow-on patents for "improvements" to their original drugs in order to extend their period of market protection. While the Hatch-Waxman Act provides generic drug manufacturers the legal framework to challenge bogus patents, including follow-on patents, reexamining the validity of patents before they are listed in the Orange Book would bolster this process.

The Solution

In order to lower costs for prescription drugs, we must boost marketplace competition. Our solution is to improve the process by harnessing the power of the private sector to challenge patents on brand name drugs, including follow-on patents based companies making disingenuous "improvements" to their drugs.

The *Second Look at Drug Patents Act* requires that the U.S. Patent and Trademark Office initiate a process to reexamine the validity of patents before they are listed in the Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book"). Entry into the Orange Book is an important step for drug patents, because it has the legal effect of blocking generic entry.

The *Act* requires brand name drug manufacturers to submit all new patents to the Official Gazette of the Patent and Trademark Office ("Gazette") within 30 days of approval. Listing patents in the Gazette serves to solicit additional information about the strength of those patents and invite patent challenges. Any patent included in the Gazette will be listed in the Orange Book on a provisional basis unless the Patent Trial Appeal Board confirms the patent to be patentable or if the patent is not challenged within a specific timeframe.

These modifications to the patent process will ease the burden on generic drug manufacturers by flagging for the public those patents most eligible for lawful challenge. The *Second Look at Drug Patents Act* provides a new tool to help bring generic drugs to market in a timelier and more efficient manner, giving consumers needed access to lower-priced prescription drugs.

The Second Look at Drug Patents Act is supported by: the Campaign for Sustainable Rx Pricing (CSRxP).