The Second Look at Drug Patents Act of 2020

Senators Patty Murray (D-WA) and John Cornyn (R-TX)

The *Second Look at Drug Patents Act* improves the process for challenging sham drug patents, removing obstacles to lower-cost generic drugs' entry to market.

The *Second Look at Drug Patents Act* requires that the U.S. Patent and Trademark Office initiate a process to facilitate reexamining 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 U.S. Patent and Trademark Office within 30 days of approval. The Director of the U.S. Patent and Trademark Office is then required to post new patents on a new U.S. Patent and Trademark Office website and in the Official Gazette of the Patent and Trademark Office ("Official Gazette"). Listing patents in this website and the Official Gazette serves to solicit additional information about the strength of those patents and invite patent challenges.

These modifications to the patent process will ease the burden on patent challengers, including generic drug manufacturers ,by flagging for the public those patents 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.

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