

## **S. 2658 Medication Affordability and Patent Integrity Act**

### **Section 1. Short Title.**

This Act may be cited as the “Medication Affordability and Patent Integrity Act”.

### **Section 2. Disclosure of Information**

This section amends the Federal Food, Drug, and Cosmetic Act to require sponsors of new drug applications and biologics license applications to certify to the Food and Drug Administration (FDA) and the United States Patent and Trademark Office (USPTO) that the information submitted to each agency is complete and consistent with the information provided to the other agency. This section also details the information to be submitted and included within the scope of the certification, including any statement or characterization of analytical or clinical data disclosed to USPTO that has been, or will be, submitted to FDA to support the approval or an application, and any statement or characterization with respect to an applicable patent submitted by the sponsor of an application to USPTO, and includes a definition of the term applicable patent.

This section also amends title 35 of the United States Code to include a defense to infringement of applicable patents for drugs and biological products if the owner of the applicable patent violates the certification-related requirements by negligently or intentionally failing to disclose any information required to be disclosed pursuant to such requirements.