Needed Patent Reforms Will Lower Drug Costs

Biologic and brand-name drug manufacturers engage in a number practices such as the use of (1) "**primary-structure and secondary-structure patent filings**"; (2) "**pay-for-delay**," and (3) "**sham citizen petitions filed with the Food and Drug Administration (FDA)**."

These practices block generic and biosimilar drugs from entering the market to compete with patented drugs. **The result is higher cost drugs for patients and health care payers like employer-sponsored self-insured health plans.**

"Primary-Structure and Secondary-Structure Patent Filings – FDA/USPTO coordination

An effective way to deter the use of "**primary-structure and secondary-structure patent filings**" is allowing the United States Patent and Trademark Office (USPTO) to coordinate with the FDA to source back the **"primary-structure filing**" to the "**secondary-structure filings**" and communicate with the FDA to seek disclosures and information relating to a "**secondary-structure filing**."

- Congress must allow the USPTO to directly engage FDA officials to ask questions about the technical details of a particular patent filing, obtain relevant information from the drug regulatory dossier, and request that FDA officials conduct additional research on a particular brand-name drug.
- **S. 2780** and **H.R. 5429 from the 118th Congress** (the *Medication Affordability and Patent Integrity Act*) would do just that by strengthening the coordination between the USPTO and the FDA.
- **S. 79** and **H.R. 1717 from the 118th Congress** (the *Interagency Patent Coordination and Improvement Act*) would also establish an Interagency Task Force between the USPTO and FDA for purposes of sharing information and providing technical assistance with respect to patents for biologic and brand-name drugs.

"Pay-for-Delay"

Congress must – once-and-for-all – stop biologic and brand-name drug companies from stifling competition by paying biosimilar and generic drug companies to delay the introduction of a biosimilar or generic version of the drug into the market (known as **"pay-for-delay**").

- **S. 142** from the 118th Congress (the *Preserve Access to Affordable Generics and Biosimilars Act*) would do this by authorizing the Federal Trade Commission (FTC) to nullify an agreement in which a biologic or generic drug company receives anything of value from a biologic or brand-name drug company to forego research, development, manufacturing, marketing, or sales of a biosimilar or generic drug.

"Sham Citizen Petitions Filed With the FDA"

Congress must also stop biologic and brand-name drug companies from manipulating the FDA's regulatory process. Here, these drug manufacturers use the FDA's "citizen petition process" as a tactic to block biosimilar and generic drugs from entering the market.

- **S. 148** in the 118th Congress (the *Stop STALLING Act*) would empower the FTC to take action against a drug manufacturer that files a "**sham citizen petition with the FDA**" with the intent to interfere with approval of a particular biosimilar or generic drug that would otherwise compete with a biologic or brand-name drug.