Interagency Patent Coordination and Improvement Act of 2023 (S. 79)
Senators Durbin (D-IL) & Tillis (R-NC)

Background: The U.S. pays the highest prices for medications in the world—on average, nearly four times higher than peer countries for many common drugs. Much attention has focused on the patent portfolios and certain tactics by brand-name manufacturers regarding their blockbuster drugs that can limit competition from lower-cost generics.

For example, concerns have been raised with "patent thickets", whereby brand-name companies obtain multiple patents on different aspects of the same product—creating litigation barriers to generic entry. Additionally, concerns have been raised with "evergreening" in which brand-name companies obtain patents for "post-approval" or secondary changes to existing drugs—such as for new formulations, delivery systems, doses, or manufacturing techniques—some of which may only provide limited patient benefit. Studies have found that 78 percent of all new drug patents cover medications already on the market. In some cases, companies have sought secondary patents to fit the phrasing in an approved label, including instances where a company obtained a patent for a specific dosing regimen based upon a study mandated by FDA. Inversely, companies have sought specific FDA label decisions based upon the language of a patent they hold (rather than for the most effective or safest dose).

While the U.S. Patent and Trademark Office (USPTO) plays an important role in issuing patents to foster innovation, the U.S. Food and Drug Administration (FDA) also plays a significant role. Among other functions, the FDA:

- Lists pharmaceutical patents in its Orange and Purple Books to clarify the patent landscape for generic/biosimilar drug applicants;
- Automatically applies a 30-month stay of approval for generic drugs when, after asserting that the patents covering a brand-name drug are not infringed, the brand initiates a patent infringement lawsuit;
- Reviews product submissions and representations from brand-name manufacturers which are often also subject to similar submissions and representations to the USPTO.

Issue: Currently, there is limited collaboration between USPTO and FDA, aside from a narrow set of responsibilities to determine eligibility for patent extensions. The agencies share interaction and jurisdiction over patent, product approval, and competition matters with pharmaceuticals. This unique dynamic could benefit from enhanced coordination and communication to ensure that rewarding innovation does not improperly forestall access to affordable medicines.

Notably, President Biden's Executive Order on Promoting Competition in the American Economy directed the FDA to send a letter to PTO enumerating and describing concerns related to unjustifiable delays in generic drug and biosimilar competition related to the patent system.

Solution: This legislation would establish a task force between USPTO and FDA to foster enhanced communication and coordination in implementing each agency's activities related to pharmaceutical patents, while respecting their distinct purviews. Including:

- Sharing information on general agency processes, standards, and methods;
- Sharing information on new technologies and scientific trends;
- Promoting access to information, as needed, on key approval dates to assess prior art; ensure accurate representations by companies between the two agencies; ensuring accuracy of patent listings; and to furnish other appropriate information.