Biologic Patent Transparency Act (S. 659)

Sponsored by Senators Susan M. Collins and Tim Kaine

Cosponsored by Senators Portman, Shaheen, Braun, and Stabenow

Biologic medicines represent a new and promising era in treatments; yet, when competing products—"biosimilars"—attempt to enter the market, they often find it impossible to navigate the extensive portfolio of patents that protect the brand product due to a lack of readily accessible information. When biosimilar manufacturers are able to uncover the web of patents, expensive litigation too often results in patents being found to be invalid or unenforceable. The *Biologic Patent Transparency Act* seeks to help increase patent transparency, promote biosimilar competition, bring needed biosimilar treatments to patients faster, and ultimately, lower drug prices for consumers.

The *Biologic Patent Transparency Act* requires the manufacturers of approved products to disclose and list patents covering their products with the FDA. By requiring patent information to be published in FDA's "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations," commonly referred to as the "Purple Book," the bill imposes transparency requirements that are similar to what are required for small molecule drugs under the Hatch-Waxman framework, which has proven successful in promoting the development and use of generic drugs. The bill also targets competition-stymieing patent thickets that delay competition without providing meaningful product improvements by restricting enforcement of patents that are issued after a biosimilar application has been submitted to the FDA. This will encourage manufacturers to apply for patents sooner, allowing prospective biosimilar manufacturers to challenge weak or invalid patents earlier in the product development process. In addition, the bill will standardize publication of the "Purple Book" and require that the FDA make enhancements to it that will promote competition.

The Biologic Patent Transparency Act:

- Codifies the publication of FDA's "Purple Book" as a single, searchable list;
- Requires additional information to be published in the "Purple Book," including:
    - Patents that claim and relate to FDA-approved biological products, including composition patents, patents claiming methods of use, and patents claiming methods of manufacture;
    - Information related to biosimilarity and interchangeability;
    - Information related to exclusivities; and
    - Approved indications;
- Limits the enforceability of late-filed patents by the biologic manufacturer when a biosimilar application has already been filed with the FDA.