

# **Biologic Patent Transparency Act**

## ***Sponsored by Senator Susan M. Collins***

Biologic medicines represent a new and promising era in treatments; yet often when competing products—“biosimilars”—attempt to enter the market, they find it impossible to navigate the extensive portfolios of patents that protect the brand product due to a lack of readily accessible information. When they 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* increases patent transparency and help biosimilar products come to market faster by requiring the manufacturers of approved products to disclose and list patents covering their products with the FDA. By requiring this patent information to be published in the Purple Book, the this bill imposes a transparency requirement that is similar what is required for small molecule drugs under the Hatch-Waxman framework, which has proven incredibly successful in promoting development and use of generic drugs.

The *Biologic Patent Transparency Act* will promote biosimilar competition, bring needed treatments to patients faster, and lower drug prices for consumers. This bill will also encourage manufacturers to apply for patents earlier and will allow prospective biosimilar manufacturers to challenge weak or invalid patents earlier in the filing process. This bill would also standardize publication of the Purple Book and require the FDA to include other information that will also promote competition, such as information about biosimilarity and exclusivity.

### **The Biologic Patent Transparency Act:**

- Codifies the FDA’s Purple Book and requires specific information to be published in it, including:
  - Patents that claim and relate to 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.
- Combats competition-stymieing patent thickets by limiting the enforceability of late-filed patents that are used to protect market monopolies.

*Many of the provisions contained in the Biologic Patent Transparency Act stem from stakeholder comments to HHS’ blueprint, which sought suggestions on how to improve the Purple Book.*