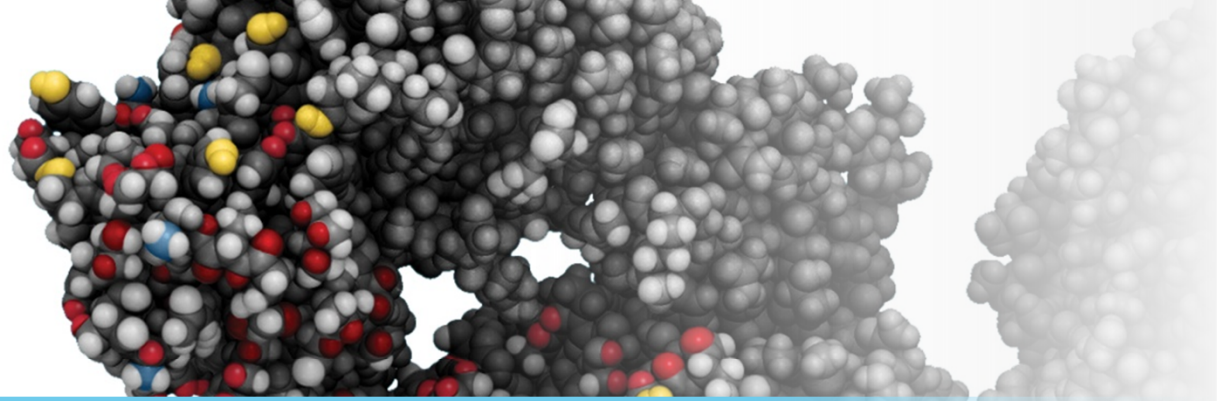
Morgan Lewis



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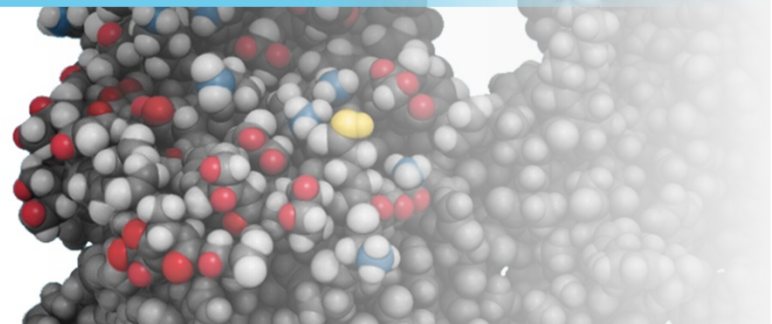
Legislative and Regulatory Updates



Senate Judiciary Committee Advances Drug Patent & Pricing Bills

- On April 3, 2025, the U.S. Senate Judiciary Committee advanced six bipartisan bills directed to drug patents and pricing to the full Senate.
  - The **Prescription Pricing for the People Act of 2025**, if passed, would require the Federal Trade Commission (FTC) to study the role of intermediaries in the pharmaceutical supply chain and provide Congress with policy recommendations.
  - The **Drug Competition Enhancement Act**, if passed, would make "product hopping" a violation of antitrust laws.
  - The **Affordable Prescriptions for Patients Act**, if passed, would limit the number of patents that can be asserted against a biosimilar applicant in a Biologics Price Competition and Innovation Act (BPCIA) litigation.
  - The **Interagency Patent Coordination and Improvement Act of 2025**, if passed, would establish an interagency task force between the FDA and USPTO to establish processes for sharing submitted information.
  - The **Stop Significant and Time-wasting Abuse Limiting Legitimate Innovation of New Generics (Stop STALLING) Act**, if passed, would grant the FTC authority to bring a civil action against those filing "sham" citizen petitions with the FDA.
  - The **Preserve Access to Affordable Generics and Biosimilars Act**, if passed, would clarify boundaries of permissible settlements in the pharmaceutical industry.

Senators Reintroduce Patent Reform Bills

- On May 1, 2025, Senators Thom Tillis (R-N.C.), Chris Coons (D-Del.), Dick Durbin (D-Ill.), and Mazie Hirono (D-Hawaii) reintroduced the bipartisan Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act.
  - The PREVAIL Act seeks to overhaul procedures at the Patent Trial and Appeal Board (PTAB), including narrowing who may initiate PTAB proceedings, limiting serial and duplicative filings, and aligning PTAB standards with those used in federal courts.
- On May 1, 2025, Senators Tillis and Coons and Representatives Kevin Kiley (R-Calif.) and Scott Peters (D-Calif.) reintroduced the bipartisan Patent Eligibility Restoration Act (PERA).
  - If passed, PERA would eliminate judicial exceptions to patent eligible subject matter and replace them with specific, defined statutory exceptions.

FDA Releases BsUFA III Regulatory Research Program Roadmap

Advancing its BsUFA III regulatory research pilot program commitments, the FDA released a research roadmap structured around research deliverables to be completed by the end of BsUFA III (9/30/2027).

Broadly aimed to advance (1) the development of interchangeable products and (2) improve the efficiency of biosimilar development, the FDA announced two areas of focus:

- **increasing the accuracy and capability of analytical and CMC characterizations** (which includes approaches for assessing and reporting product quality attributes, characterizing relationships between product quality attributes and clinical outcomes, improving new analytical technologies, and assessing the impact of differences of product presentations and container closure systems on product protection, safety, compatibility, and performance); and
- **developing alternatives to/reducing the size of studies in humans** (which includes alternatives to the comparative immunogenicity assessment (whether conducted as part of comparative clinical studies or switching studies), alternatives to clinical bridging data from non-U.S. approved comparators, increased use of PD biomarkers, and assessments of which user interface differences are likely to affect the safe and effective use of interchangeable products and related assessment methodologies).

In addition to highlighting potential research opportunities, this roadmap also highlights areas of likely policy development and attention going forward.

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