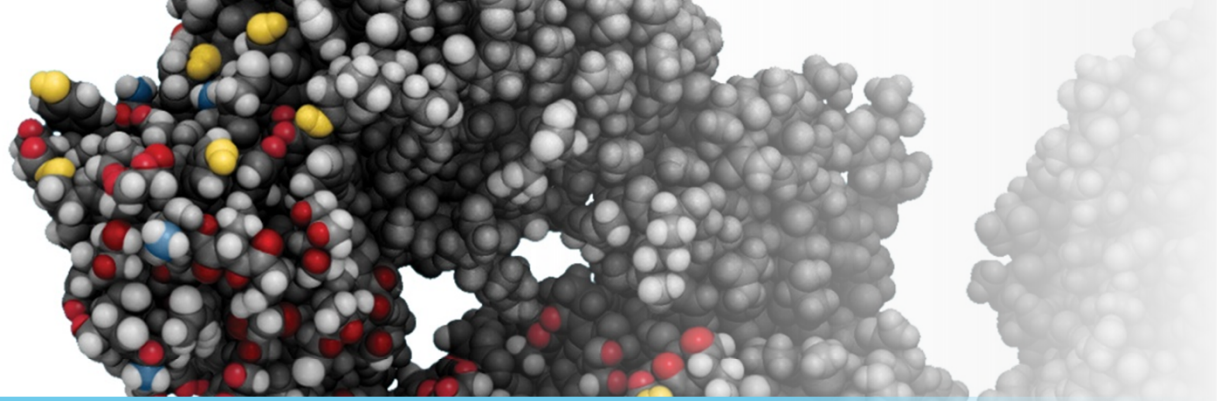
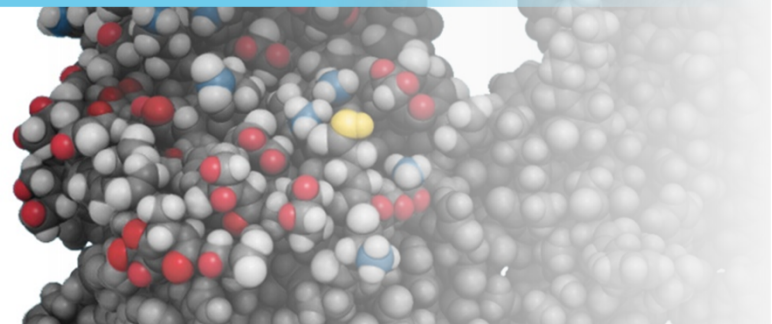
Morgan Lewis



BLOCKBUSTER BIOLOGICS REVIEW ISSUE 28

Legislative and Regulatory Updates



Senators Reintroduce "Biosimilar Red Tape Elimination Act"

- On June 4, 2025, Senators Mike Lee (R-Utah), Rand Paul (R-Ky.), Maggie Hassan (D-N.H.), and Ben Ray Luján (D-N.M.) reintroduced the bipartisan Biosimilar Red Tape Elimination Act.
  - The Biosimilar Red Tape Elimination Act was previously introduced in 2022 and sought to stop FDA from requiring biosimilars to conduct "unnecessary" switching studies in order to obtain an interchangeability designation.
  - If passed, the current version of the Biosimilar Red Tape Elimination Act would automatically deem biosimilars interchangeable with their name-brand counterpart once the biosimilar receives FDA approval.

Senators Introduce Bill to Limit "Patent Thickets"

- On July 15, 2025, Senators Peter Welch (D-Vt.), Amy Klobuchar (D-Minn.), and Josh Hawley (R-Mo.) introduced the bipartisan Eliminating Thickets to Improve Competition (ETHIC) Act.
  - If passed, the ETHIC Act would limit pharmaceutical companies to asserting only one patent per "patent group" in an infringement action.
  - A "patent group" would include commonly owned patents or applications that are identified on or subject to terminal disclaimers to obviate obviousness-type double patenting of another commonly owned patent.

FDA Interchangeability Workshop

- On September 19, 2025, the FDA will hold a public scientific workshop on the development of interchangeable products. Planned topics for discussion include:
  - Future needs for the development of interchangeable biosimilars.
  - Analytical considerations around interchangeability.
  - User interface and human factors considerations around interchangeability.
- Announced speakers include FDA staff as well as representatives of industry groups.
- Within one year of the workshop, the FDA plans to issue a draft strategy document for public comment, outlining specific actions it intends to take to facilitate the development of interchangeable biosimilars.

FDA Announces FY 2026 Biosimilar User Fees

- Consistent with typical agency practice, FDA recently announced BsUFA III user fees applicable to FY 2026, which will go into effect as of October 1, 2026.
- Between FY 2025 and FY 2026, Biological Product Development (BPD) fees remain unchanged (Initial BPD: $10,000; Annual BPD: $10,000; Reactivation: $20,000).
- Application fees for FY 2026 are reduced compared to FY 2025:
  - $1,200,794 for a biosimilar application where clinical data are required (compared to the $1,471,118 fee appliable to FY 2025).
  - $600,397 for a biosimilar application where clinical data are not required (compared to the $735,559 fee applicable to FY 2025).
- Program fees are reduced to $206,097 for FY 2026 (compared to the $256,168 fee applicable to FY 2025).

FDA Finalizes Formal Meetings Guidance

- FDA recently published (and finalized) the BsUFA guidance "Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products."
- This publication finalizes the draft version of the guidance published on August 11, 2023, with relatively minor changes between its draft and final versions.
- The guidance describes differences between formal BsUFA and BPD meeting types and issues related to meeting format, requests, packages, responses, and conduct issues.

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