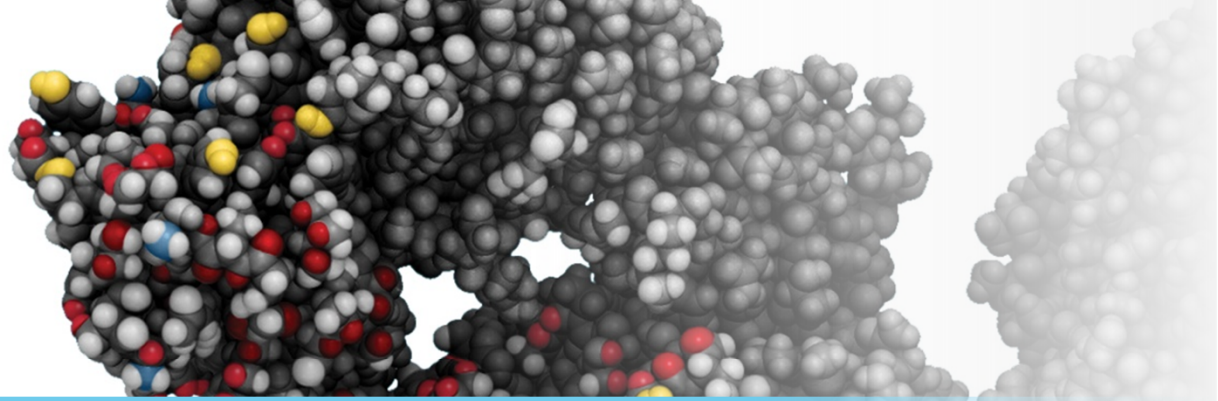
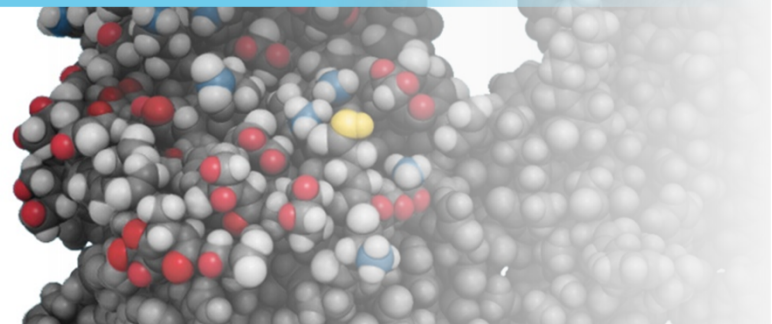
Morgan Lewis



BLOCKBUSTER BIOLOGICS REVIEW ISSUE 19

Legislative and Regulatory Updates



Legislative and Regulatory Updates

- **On February 9, 2023, the Senate Judiciary Committee reported on the following three acts:**
  - The Preserve Access to Affordable Generics and Biosimilars Act (S. 142)
    - Would prohibit anticompetitive "pay-for-delay deals" that prevent or delay the introduction of affordable generics, and target "reverse payment" settlement agreements that are categorized as "allow[ing] a branded company to share its monopoly profits with the generic company as a way to protect the branded company's monopoly" and "unduly delay the marketing of low-cost generic drugs contrary to free competition, the interests of consumers, and the principles underlying antitrust law."
  - The Stop STALLING Act (S. 148)
    - Seeks to deter branded pharmaceutical companies from filing what it claims is a "sham" citizen petition with the FDA in order to interfere with the regulatory approval process for competitors' generics and biosimilars.
  - The Affordable Prescriptions for Patients Act of 2023 (S. 150).
    - Would curb drug companies' purported abuse of patents through "product hopping," where companies extend exclusivity by switching patients to a new, slightly changed, version of the branded drug while the older version succumbs to generics.

Legislative and Regulatory Updates

- **On February 22, 2023, Sen. Elizabeth Warren, along with Sen. Bernie Sanders and Representatives Katie Porter and Pramila Jayapal, sent a letter to Kathi Vidal, director of the USPTO, over Merck's Keytruda® (pembrolizumab).**
  - They expressed concern over Merck's efforts to patent a subcutaneous version of the currently infused drug.
  - The members of Congress also opined that subcutaneous injections do not represent novel improvements for drugs, as "medications have been injected under the skin since insulin was discovered in 1921."
  - The members of Congress urged Vidal to "give close scrutiny to any of Merck's requests for new patents for Keytruda, and reject those that do not clearly meet the agency's standards."

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