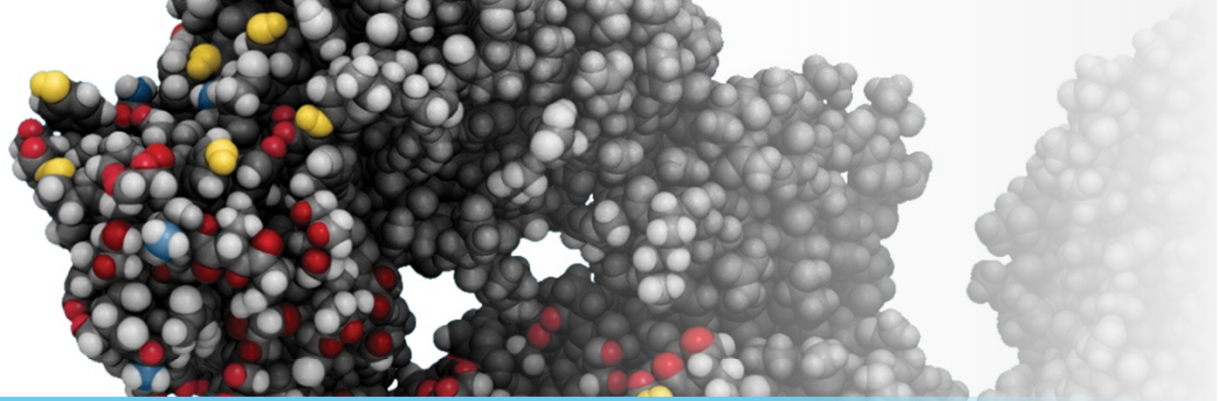
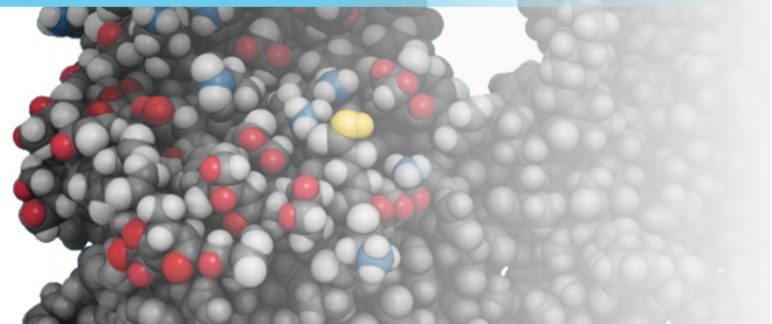
Morgan Lewis



BLOCKBUSTER BIOLOGICS REVIEW ISSUE 21

Legislative and Regulatory Updates



Senate and House Introduce Bills Titled "The Medication Affordability and Patent Integrity Act" to Lower Prescription Drugs

- **On September 13, 2023, Sen. Maggie Hassan (D-NH) and Sen. Mike Braun (R-IN) introduced a bill (S 2780) that would require pharmaceutical drug and biological product manufacturers to provide consistent information to both the FDA and US Patent and Trademark Office.**
  - A parallel bill (HR 5429) was introduced in the House by Reps. Annie Kuster (D-NH) and Diana Harshbarger (R-TN).
  - According to the Senators, drug manufacturers are "able to unfairly extend the exclusivity period for a drug by submitting partial information for their initial patent, in order to help secure subsequent patents down the road" because there is "incomplete coordination" between the FDA and USPTO.
  - The bill seeks to amend the existing Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 355(b)) and Public Health Service Act (PHSA) (42 U.S.C. § 262) by adding new certification and disclosure requirements for drug approval.
    - The sponsor of any application submitted or approved under the FDCA or PHSA would need to:
      - certify to both the FDA and USPTO that information submitted to each agency is consistent with information submitted to the other; and
      - submit to the USPTO any information "material to patentability" of "applicable patents" that it submitted to the FDA as part of its drug application or subsequent communications with the FDA.

Senate and House Introduce Bills Titled "The Medication Affordability and Patent Integrity Act" to Lower Prescription Drugs (cont.)

- The Act defines "the information" to include:
  - "any statement or characterization of analytical or clinical data" disclosed to the USPTO that has been or will be used in a submission to the FDA to support approval of a drug application;
  - "any statement or characterization with respect to an applicable patent, including any statement or characterization of prior art" submitted to the USPTO in support of patentability; and
  - "other information, as the Secretary or the Secretary of Commerce may require."
- The bill also seeks to amend the Patent Act to add a new defense to patent infringement based on a sponsor's failure to comply with the disclosure requirements under the Act.
- These legislative proposals follow the ongoing collaboration between the USPTO and FDA arising out of the July 2021 Executive Order on "*Promoting Competition in the American Economy,*" including a February 2023 panel discussion and related federal register notice regarding the duties of disclosure and reasonable inquiry.

FDA Focus on Interchangeability & Labeling

- In September, the FDA issued a newly revised draft guidance regarding "Labeling for Biosimilar and Interchangeable Biosimilar Products"
- In addition to providing valuable general guidance on labeling for these products, this revision announces a change in approach from the FDA regarding the inclusion of previously recommended "Biosimilarity Statements" and "Interchangeability Statements."
- In the revised guidance, the FDA now recommends using the biosimilarity statement for all biosimilars (including interchangeable biosimilars) in the products' prescribing information, signaling that a uniform approach to labeling for these two product classes would be appropriate.
- Although this proposed change would not impact pharmacy-level substitution practices applicable to interchangeable biosimilars, it reflects an ongoing assessment by the FDA of the differences between biosimilars and interchangeable biosimilars in general.
- Comments on the draft guidance are due on November 17, 2023.

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