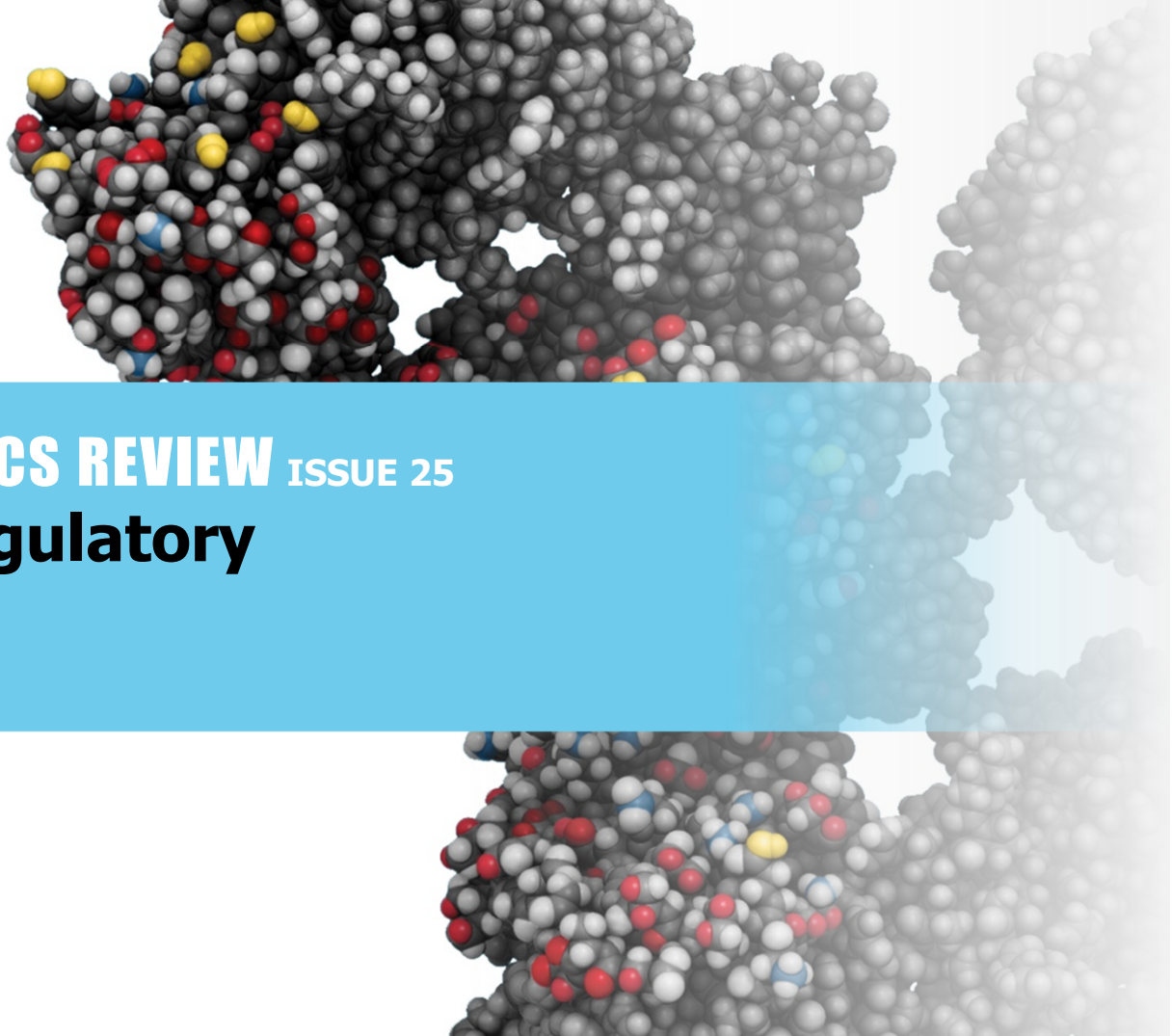


Morgan Lewis



BLOCKBUSTER BIOLOGICS REVIEW ISSUE 25

Legislative and Regulatory Updates

Senate Passes Affordable Prescriptions for Patients Act to Limit the Number of Patents in Biosimilar Litigation.

- On July 11, 2024, the Senate unanimously passed a bipartisan bill titled the Affordable Prescriptions for Patients Act. The bill sets a cap of 20 patents in certain categories that can be asserted by a Reference Product Sponsor (RPS) in Biologics Price Competition and Innovation Act (BPCIA) litigation.
- Specifically, the bill covers patents that:
 - (i) claim the biological product subject to the biosimilar application or a method or product used in making that biological product;
 - (ii) were included on the RPS's paragraph (3)(A) patent list; and
 - (iii) have an actual filing date more than four years after the date on which the RPS was approved or include a claim to a method in a manufacturing process that is not used by the RPS.
- The bill does not limit the number of patents an RPS can include in its paragraph 3(A) patent list during the patent dance. Instead, the bill limits the number of patents that can be asserted in BPCIA litigation—the actual complaint for patent infringement, not the RPS's patent list, kicks off the patent dance.
- The House has not yet taken up the bill and was initially scheduled to consider this legislation the week of September 23. However, the bill was never called up.
- It remains to be seen whether the bill will make it back onto the House legislative agenda before the 118th Congress ends on January 3, 2025.

Contacts



Christopher J. Betti, Ph.D.
Chicago
T: +1.312.324.1449
christopher.betti@morganlewis.com



Kelly A. Plummer, Ph.D.
Chicago
T: +1.312.324.1490
kelly.plummer@morganlewis.com



Maarika L. Kimbrell
Washington, DC
T: +1.202.739.5348
maarika.kimbrell@morganlewis.com



Maria E. Doukas
Chicago
T: +1.312.324.1454
maria.doukas@morganlewis.com



Margaret C. Harney
Chicago
T: +1.312.324.1727
margaret.harney@morganlewis.com



Jennifer Patritti Cram, Ph.D.
Houston
T: +1.713.870.5173
jennifer.patriticram@morganlewis.com