Biosimilars Act Remains Law After Supreme Court Review of the Affordable Care Act

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The Supreme Court today upheld the Affordable Care Act, which includes the Biologics Price Competition and Innovation Act (Biosimilars Act). The Biosimilars Act provides an accelerated pathway for the approval of follow-on biological products (“biosimilars”).

Survival of the Biosimilars Act means that a developer of a biosimilar product retains the option to request FDA approval of the product using the accelerated pathway rather than by application for a full biologics license.

If you have questions about how the Biosimilars Act may impact your patent strategy, please contact your Banner & Witcoff attorney or any member of the firm’s Life Sciences industry group.

The text of the Biosimilars Act can be found here.

Draft FDA guidance documents for demonstrating biosimilarity can be found here.

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