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Biosimilars and the Biologics Price Competition and Innovation Act (BPCIA)

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This practice note discusses biosimilars, the litigation process set up by the Biologics Price Competition and Innovation Act (BPCIA) to facilitate resolution of patent disputes between reference product sponsors and biosimilar manufacturers. This note also touches on related trends, such as the potential use of inter partes review proceedings by biosimilar manufacturers as an alternative or in addition to litigation. The BPCIA provides an abbreviated pathway for companies to bring biologic drugs to market that are “biosimilar” to previously approved branded reference products by relying on clinical studies that were performed by the reference product sponsor (RPS).

Related People



April Abele Isaacson
t 415.273.8306
aisaacson@ktslaw.com