



# THINK FORWARD

## Federal Circuit Interprets Key Provisions Governing Biosimilars

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The Biologic Price Competition and Innovation Act (“BPCIA”) was enacted in 2010 to provide an abbreviated pathway for FDA approval of biologic products (“biosimilars”) deemed sufficiently similar to products already on the market. Today, the Federal Circuit issued its first ever decision interpreting two key provisions in the BPCIA.

First, the court ruled that the BPCIA does not require a biosimilar applicant to disclose its biosimilar application to the reference product sponsor or otherwise engage in the exchange of patent-related information concerning the application (which some commentators have referred to as the “patent dance”). Instead, a biosimilar applicant can opt out of these exchanges and face the possibility of an immediate patent infringement action.

Second, the court ruled that a biosimilar applicant must wait until FDA approval of its biosimilar application to first give a reference product sponsor the required 180-day notice of commercial marketing. As a result, today’s decision adds 180 days of exclusivity to the 12 years that branded biologics already receive.

Brinks can help your company with the application of the BPCIA, including litigation relating to biosimilars. If you have any questions or wish to discuss how this decision may impact your company, please contact a member of our BioPharma Practice Group.