

# WORLD BIOSIMILARS CONFERENCE

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### Navigating the legal and IP challenges to biosimilar market entry

Joanna T Brougher  
BioPharma Law Group PLLC, USA

The One June 12, 2017, the United States Supreme Court, in a unanimous opinion, reversed the Federal Circuit in *Sandoz Inc. v. Amgen Inc.*, interpreting two “patent dance” provisions of the Biologics Price Competition and Innovation Act of 2009 (“BPCIA”). This decision permits manufacturers of biosimilars to begin marketing their biosimilar product prior to FDA approval and deprives the owner of the reference product of a means to force disclosure of the method used to manufacture the biosimilar. While the Supreme Court’s decision is largely seen as a victory for manufacturers of biosimilars who now have fewer obstacles to overcome in reaching the market, there are still many

unanswered questions remaining following the decision.

Some of the major topics that will be covered are:

- Overview of the BPCIA Patent Dance and recent court decisions
- Review of inter partes review (IPR) procedures and anti-patent climate
- Examine challenges to biosimilar market entry, including, constitutional challenges, sovereign immunity, anti-trust issues, and current legislations

joannabrougher@gmail.com