



THINK FORWARD

First-Ever Biosimilar Application Approved by FDA Under BPCIA

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Friday marked the FDA's first-ever approval of a biosimilar application under the Biologics Price Competition and Innovation Act (BPCIA), 42 U.S.C. § 262. The BPCIA was enacted back in 2010 as part of the Patient Protection and Affordable Care Act, and establishes a streamlined process for obtaining FDA approval to market biosimilar drugs within the United States. While this process has been available for several years, there have been few biosimilar applications filed under the BPCIA given perceived ambiguities associated with what is required by the FDA to achieve approval. In 2014, Sandoz filed the first-ever application under the BPCIA for its biosimilar filgrastim, a biosimilar of Amgen's NEUPOGEN® used to decrease incidence of infection and treat neutropenia in cancer patients, among other things. On Friday, the FDA approved Sandoz's application to commercially market filgrastim in the United States.

Nonetheless, pending litigation in the Northern District of California may impact when Sandoz actually initiates commercial marketing of filgrastim. On February 5, 2015, Amgen (which markets NEUPOGEN®) filed a motion seeking a preliminary injunction to prevent Sandoz from commercially marketing filgrastim upon FDA approval. (See *Amgen Inc. v. Sandoz Inc.*, Civ. No. 3:14-cv-04741 (N.D. Cal.), D.I. 56). The hearing on Amgen's motion is currently scheduled for March 13, 2015. In the meantime, Sandoz has agreed not to launch filgrastim in the United States until the earlier of April 10, 2015, or a ruling in Sandoz's favor by the court. (*Id.* at D.I. 64). Thus, it remains to be seen when Sandoz will be able to bring its biosimilar product to market, notwithstanding approval by the FDA.

This approval marks a significant event for the U.S. biosimilar market, and should encourage companies to consider using the BPCIA going forward.

If you have any questions or wish to discuss how this decision may impact your company, please contact a member of our [Biotechnology/Pharmaceutical](#) group.