

## CLIENT ALERT

### Sandoz Launches First U.S. Biosimilar

September 4, 2015

On Thursday, Sandoz launched the first U.S. biosimilar after the Federal Circuit's *Amgen v. Sandoz* decision on Wednesday to deny Amgen's request to extend the injunction that had prevented the launch. The injunction barring launch was set to expire and Amgen moved to extend the stay while the full Federal Circuit considers Amgen's petition for *en banc* review of its July 21 ruling that would allow the launch. The motion was denied without comment, in a 2-1 split decision. [See Order](#).

This represents the latest development in an ongoing litigation over the first biosimilar to gain approval in the U.S. Sandoz had filed an abbreviated biologics license application (aBLA) with the FDA. Once the application was accepted, Sandoz notified Amgen of its intention to launch once it gained approval. Sandoz also refused to provide its aBLA and manufacturing information to Amgen by the end of the statutory deadline. On this basis, Amgen filed suit in the Northern District of California. There, the court held that (i) disclosure of a biosimilar applicant's Biologic License Application (BLA) and proprietary manufacturing information to the reference product sponsor is permissive; and (2) that a biosimilar applicant is required to give the reference sponsor 180-day notice of the first commercial marketing of the biosimilar only **after** the biosimilar is approved by the FDA. [See our previous Client Alert: "District Court's Decision Paves the Way for the First U.S. Biosimilar."](#)

As we [previously reported](#), the Federal Circuit had held that Sandoz did not violate the Biologics Price Competition and Innovation Act (BPCIA) by not disclosing its aBLA and the manufacturing information by the statutory deadline. Amgen petitioned the full Federal Circuit to revisit that interpretation of the BPCIA and moved to continue the injunction preventing Sandoz's launch pending that determination.

Amgen's petition for *en banc* review is still pending.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

**Keith J. Harrison**

Partner – Washington, D.C.  
Phone: +1.202.624.2560  
Email: [kharrison@crowell.com](mailto:kharrison@crowell.com)

**Terry Rea**

Partner – Washington, D.C.  
Phone: +1.202.624.2620  
Email: [trea@crowell.com](mailto:trea@crowell.com)

**Anne Elise Herold Li**

Partner – New York  
Phone: +1.212.895.4279

Email: [ali@crowell.com](mailto:ali@crowell.com)