BPCIA: AMGEN BEGINS THE PATENT DANCE WITH ABBVIE

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Biosimilars/Follow-on Biologics Alerts

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On November 25, 2015, Amgen Inc. ("Amgen") announced it submitted its first biologics license application ("BLA") to the FDA under the Section 351(k) biosimilar approval pathway provided in the Biologics Price Competition and Innovation Act ("BPCIA"). Amgen's BLA seeks approval for its biosimilar of AbbVie's top-selling arthritis drug Humira® (adalimumab). Amgen's biosimilar is temporarily known as ABP 501.

Although this BLA is the first biosimilar application submitted by Amgen, Amgen is no stranger to the BPCIA and its "patent dance" provisions. Amgen was involved in a dispute with Sandoz Inc. ("Sandoz") for most of 2015 regarding Sandoz's product Zarxio®—a biosimilar of Amgen's Neupogen®. *See* FDA Approves First Biosimilar: Sandoz's Zarxio®. The primary issue in this dispute was whether the "patent dance" provisions of the BPCIA were optional. Amgen argued these provisions were mandatory; however, the Federal Circuit ultimately ruled against Amgen and held certain "patent dance" provisions are optional. *See, e.g.*, BPCIA Statute: Patent Dance is Optional, But Opting Out has Consequences; BPCIA Statute: Has the Music Stopped or Will the Patent Dance Continue?

In anticipation of its BLA submission for ABP 501, Amgen filed two *inter partes* review ("IPR") petitions with the Patent Trials and Appeals Board ("PTAB") on June 26, 2015. These petitions seek to invalidate two of AbbVie's Humira®–related patents. A decision as to whether the PTAB will institute these IPRs is expected at the end of this month.

Amgen's ABP 501 BLA includes analytical, clinical, and pharmacokinetic data. Earlier this year, Amgen completed phase III comparative efficacy and safety studies in patients with moderate-to-severe plaque psoriasis and moderate-to-severe rheumatoid arthritis. Amgen used the results of these studies to argue: (1) ABP 501 has a safety profile that is comparable to Humira® and (2) ABP 501 is clinically equivalent to Humira®.

It is currently unclear how Amgen will handle its ABP 501 BLA submission. First, Amgen has not stated whether it will seek an interchangeable designation. Second, Amgen has not commented on whether it will take part in the "patent dance." As a BLA applicant, Amgen may now have a different view regarding the need to follow these provisions, particularly since the Federal Circuit held some provisions are optional. Third, Humira® is approved for several indications. At this point, Amgen has only submitted comparative data to the FDA for two of the approved indications. Amgen may try to seek approval for the other indications through extrapolation from the provided data. Alternatively, Amgen may maintain a more narrowly-tailored approach, focusing on moderate-to-severe plaque psoriasis and moderate-to-severe rheumatoid arthritis.

Additionally, it is still unknown whether either Amgen or Sandoz will file a petition for ceritorari to the Supreme Court regarding the Federal Circuit's holding and whether this would have any impact on Amgen's strategy regarding its own ABP 501 BLA submission.

K&L Gates will continue to monitor Amgen's ABP 501 BLA submission and IPRs directed to two of AbbVie's Humira®-related patents to see what developments may arise.

