

4th International Conference and Exhibition on

Biologics & Biosimilars

October 26-28, 2015 Baltimore, USA

U.S. biosimilars – The courts interpret BCPIA steps

Denise M Kettelberger
Sunstein Kann Murphy & Timbers LLP, USA

SANDOZ filed an aBLA seeking the first approval of a U.S. biosimilar, a filgrastim product. AMGEN's Neupogen® was the reference product. U.S. biosimilar companies closely followed progress of the first product to use the U.S. Biosimilar law (Biologics Price Control and Innovation Act). Surprisingly, SANDOZ did not proceed through the multi-step aBLA pathway of the BPCIA's patent dispute resolution system, choosing instead to notify AMGEN of the aBLA filing, expected approval date, and intended launch. Instead of the BCPIA's elaborate process for confidential information exchange and resolution of patent disputes, SANDOZ opted out of the process and did not provide AMGEN with its aBLA application. Because SANDOZ failed to provide its application and manufacturing process, AMGEN was entitled to sue SANDOZ for patent infringement under non-compliance sanctions provided in BCPIA steps. AMGEN sued SANDOZ for unfair competition; conversion; and infringement of AMGEN's patents. The District Court dismissed unfair competition and conversion claims due to its interpretation of BPCIA, finding SANDOZ did not act unlawfully. On appeal to the Federal Circuit, the BCPIA was again interpreted in *Amgen v. Sandoz*, decided July 21, 2015. The Court reviewed SANDOZ's failure to comply with the first step: applicant "shall provide" its application and manufacturing process; 180 day notice of intent to market; and whether BCPIA steps are optional or mandatory. The Court found the BCPIA steps to be *required* when the aBLA path is chosen, but not when the applicant chooses not to use the BCPIA. Federal Circuit en banc review was requested.

Biography

Denise M Kettelberger received her PhD from the University of Maryland School of Medicine, completed Postdoctoral studies at Baylor College of Medicine with Bert O'Malley, and moved into patent law as DNA products advanced, and joined Pravel, Gambrell as a patent agent. A former Merchant & Gould partner, she recently joined Sunstein Kann Murphy & Timbers LLP, a premier patent firm in Boston. Active in the American Intellectual Property Law Association, she is a frequent speaker on biotechnology patent issues.

dkettelberger@sunsteinlaw.com

Notes: