
Health Law Daily Wrap Up

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By Kathryn S. Beard, J.D.

Biosimilar manufacturers will soon have a definitive answer on the timing of giving notice of commercial marketing, thanks to the Supreme Court. On January 13, 2017, the Court granted and consolidated Sandoz, Inc.’s petition for writ of certiorari and Amgen, Inc.’s conditional cross-petition for writ of certiorari. The dispute appeals the Federal Circuit’s July 21, 2015 decision holding that Amgen was entitled to an additional 180-day marketing exclusivity period because of Sandoz’s late notification of its intention to market a biologic product that is biosimilar to Amgen’s Neupogen® (see Court interprets biosimilar ‘enigma’ in favor of abbreviated biologic license applicant, July 22, 2015).

The Court also granted Apotex, Inc.’s motion for leave to file a brief as amici curiae; Apotex was involved in a similar dispute with Amgen (see Biosimilar applicant must give 180-day post-licensure notice to reference sponsor, July 6, 2016), though the Court denied Apotex’s petition for writ of certiorari earlier this term (see SCOTUS denies cert in biosimilar licensing dispute, December 12, 2016).

The Biologics Price Competition and Innovation Act (BPCIA), which was passed in 2010 as sections 7001-7003 of the Patient Protection and Affordable Care Act (ACA) (P.L. 111-148), created an abbreviated pathway for FDA approval of a "biosimilar" biologic product. Amgen originally brought suit against Sandoz in federal court asserting various violations of Amgen’s approved license for its cancer-fighting biologic Neupogen (filgrastim) and infringement of Amgen’s patent for a particular method of using filgrastim. The Court will be hearing arguments relating to Sandoz’s question regarding the 180-day notice of commercial marketing and Amgen’s cross-petition on the optionality of a process to settle patent disputes known as the "patent dance" (see Shall we dance? Biosimilars step toward new legal and regulatory future, March 31, 2016).

Makeup of the Court. Since the February 13, 2016, death of Justice Antonin Scalia, there have been eight Justices sitting on the Court. President Barack Obama’s nominee to replace Scalia, D.C. Court of Appeals Chief Judge Merrick Garland, was not considered by the Senate; President-elect Donald Trump plans to nominate a successor early into his term. In order to receive a vote in cases pending before the Court, a Justice must be seated on both the day of the oral argument and the day the written decision is released. Trump’s nominee will only be part of the decision if he or she is confirmed and duly sworn in before the oral arguments, which are not yet scheduled.

Companies: Sandoz, Inc.; Amgen Inc.; Amgen Manufacturing Limited; Apotex, Inc.