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IP Newsflash

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FEDERAL CIRCUIT CASES

Federal Circuit Denies *En Banc* Rehearing of Biosimilar Opinion in *Amgen v. Sandoz*

Today, the Federal Circuit denied rehearing of a battle over certain provisions of the Affordable Care Act's (ACA) biosimilars pathway, leaving intact a panel opinion that certain notice provisions by the biosimilar applicant were optional. Many experts had expected that the court would grant *en banc* review, in part, because the original panel decision was fractured and included three separate opinions.

The original panel opinion interpreted two notice provisions in the Biologics Price Control and Innovation Act (BPCIA), a component of the ACA. At issue was Sandoz's decision not to comply with the first provision of the law, which states that the biosimilar applicant "shall" provide to the reference product sponsor a copy of its application and manufacturing information. Sandoz contended, and the court ultimately agreed, that despite using the word "shall," Congress did not intend to make these disclosures mandatory, because the law also provided remedies for sponsors faced with non-disclosure from an applicant.

The panel also interpreted another provision of the law, requiring that the biosimilar applicant provide 180 day notice to the product sponsor that it intended to enter the marketplace. The panel held that biosimilar makers can only provide the BPCIA's 180-day notice of commercial marketing after their product is licensed, and that this notice is mandatory when biosimilar makers do not participate in the so-called patent dance.

It is possible that Amgen and Sandoz will seek review by the U.S. Supreme Court, but it is not immediately clear whether either company will do so.

Amgen Inc. et al. v. Sandoz Inc., Case No. 15-1499 (Fed. Cir. Oct. 16, 2015).

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