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Federal Circuit Interprets Biosimilars Law in *Amgen v. Sandoz*

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In a seriously fractured decision, the Federal Circuit construed the provisions of the Biologics Price Control and Innovation Act (BPCIA or Act) in *Amgen Inc. et al. v. Sandoz Inc.* In doing so, the court limited the information available to biologic drug makers regarding a competitor's application for a biosimilar product (adopting Sandoz's argument). On the other hand, the decision extended the statutory exclusivity period enjoyed by innovator biologic drug makers relating to when the biosimilar applicant can enter the marketplace (as Amgen argued).

The BPCIA is a component of the Patient Protection and Affordable Care Act commonly known as "Obamacare" and provides for the first time in the U.S. an abbreviated pathway for FDA approval of so-called "biosimilar" drugs, generic versions of biologic drugs. The Act contains complicated litigation provisions that have come to be termed the "patent dance" that prescribe how the parties (termed the "reference product sponsor" and the "biosimilar applicant") decide which patents will be litigated during the time prior to FDA approval.

The case arose over Amgen's drug Neupogen® (filgrastim) that was the subject of a biosimilar application by Sandoz. At issue was Sandoz's decision not to comply with the first provision of the BPCIA, which states that the biosimilar applicant "shall" provide to the reference product sponsor a copy of its application and also manufacturing information (because it was recognized that patents related to manufacturing might be at issue between the parties). Sandoz contended that despite using the word "shall" Congress did not intend to make these disclosures mandatory, because the Act also provided remedies for reference product sponsors faced with nondisclosure from the biosimilar applicant. The district court sided with Sandoz in its interpretation of the BPCIA, that these remedy provisions indicate that, taken as a whole the Act does not force the biosimilar applicant to make these disclosures. The Federal Circuit affirmed this construction of these provisions of the Act.

Also at issue was the interpretation of another provision of the BPCIA, that the biosimilar applicant provide 180 day notice to the reference product sponsor that it intended to enter the marketplace. Sandoz provided this notice prior to obtaining FDA approval, which the district court found effective notice. The Federal circuit agreed with Amgen that the Act does not permit marketing notice until after a biosimilar applicant has received FDA approval. The Sandoz biosimilar, to be marketed under the brand name Zarxio® obtained FDA approval on March 5, 2015, and pursuant to the Federal Circuit's decision will be available for marketing on September 2, 2015.

The opinion was written by Judge Lourie, who was able to persuade Judge Chen to his point of view regarding the interpretation of whether disclosure of the biosimilar application was mandatory, and to persuade Judge Newman to his opinion that the law prevents a biosimilar applicant from giving marketing notice until after the FDA has approved the biosimilar application. Each of these judges wrote separate opinions reflecting partial concurrence and partial dissent, which gives both parties a basis for *en banc* review and, if necessary, petitions for *certiorari*.

Decided July 21, 2015. The opinion can be found at http://www.cafc.uscourts.gov/images/stories/opinions-orders/15-1499.Opinion.7-17-2015.1.PDF.

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