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Patent Litigation

ALERT

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Federal Circuit Interprets BPCIA for First Time

by Kathleen Gersh, Senior Counsel

The U.S. Court of Appeals for the Federal Circuit today decided issues of first impression relating to the statutory interpretation of the Biologics Price Competition and Innovation Act of 2009 (BPCIA). In a split decision in *Amgen Inc. v. Sandoz Inc.*, Judge Lourie, writing for the court, analogized the statute to the oft-quoted comparison Winston Churchill once used to describe Russia, as "a riddle wrapped in a mystery inside an enigma." Judge Lourie wrote: "That is this statute. In these opinions, we do our best to unravel the riddle, solve the mystery, and comprehend the enigma."

Bottom line: the "patent dance" is optional. The Federal Circuit decided that it is not a violation of the BPCIA for a biosimilar applicant (in this case, Sandoz) to refuse to provide the innovator with access to its biosimilar application and the manufacturing information by the statutory deadline, agreeing with Sandoz that the statute expressly contemplates this.

Second, the court ruled that when a biosimilar applicant fails to share its application and manufacturing information with the innovator by the statutory deadline, the applicant may not market its biosimilar drug before 180 days from giving the innovator notice of its approved, FDA-licensed product. In this situation, that notice is mandatory. On this point, the court agreed with Amgen, pointing out that until the biosimilar application has been approved (licensed) by the FDA, the product, its uses, and its manufacture can change. "Requiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief."

In the underlying case, Sandoz had given Amgen notice of commercial marketing of Zarxio, its biosimilar to Amgen's Neupogen (filgastim), both before and after receiving its FDA license. While the court ruled that the first notice was ineffective since it was before Sandoz received FDA licensure, it found that the second notice, dated March 6, 2015, was operative. Applying the 180 days, the court extended the injunction pending appeal against Sandoz through September 2, 2015. Sandoz may not market Zarxio before that date.

This is the first opportunity the Federal Circuit has had to weigh in on the statutory provisions of the BPCIA. The three-judge panel was split, with Judges Newman and Chen filing separate opinions concurring in part and/or dissenting in part. The court's statutory

interpretation is important not just to this case, but to all cases arising under the BPCIA. Of course, this may not be the end for Sandoz and Amgen. Review by the Federal Circuit sitting *en banc* or even review by the United States Supreme Court remain as possibilities.

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