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Client Alert

Federal Circuit Stops the Launch of the First U.S. Biosimilar Pending Appeal

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Just when the first biosimilar was poised to hit the lucrative U.S. market, the Federal Circuit put the brakes on ZARXIO®, Sandoz's biosimilar based on Amgen Inc.'s blockbuster Neupogen®. On Tuesday, the Federal Circuit temporarily blocked Sandoz, Inc. from selling ZARXIO®, saying the product can't be sold until the court resolves a dispute over information-sharing requirements of the Affordable Care Act's biosimilars pathway.

In a terse, *per curiam* order, the Circuit court offered no explanation for its granting an injunction on the first U.S. biosimilar while the appeal of the district court's decision is pending. That decision rejected Amgen's arguments, which were, essentially, that Sandoz is hiding the ball by not handing over the information that it's required to disclose under the Biologics Price Competition and Innovation Act (BPCIA), which, in turn, prevents Amgen from digging through that information to see whether it has a patent-infringement case against the biosimilar maker.

On January 14, 2015, ZARXIO® made history as the first U.S. biosimilar approved by the U.S. Food and Drug Administration (FDA). See our previous Client Alert: *Three Take-Aways from Novartis' Historic First U.S. Biosimilar Approval* (Mar. 11, 2015). In early March, the district court in *Amgen v. Sandoz*, Case No. 3:14-cv-04741-RS heard arguments on the parties' disputes of the disclosure requirements imposed by the new biosimilar pathway. The district court sided with Sandoz on its interpretation of the portion of BPCIA governing the disclosure requirements imposed on biosimilar manufacturers prior to sale of a biosimilar product. See our previous Client Alert: *District Court's Decision Paves the Way for the First U.S. Biosimilar* (Mar. 23, 2015). The district court also rejected Amgen's interpretation of the statute that would have required Sandoz to wait 180 days from approval of the biosimilar product before going to market. Instead, the district court found Sandoz was within its rights to resist sharing certain information with Amgen as part of the BPCIA's so-called patent dance.

One of the main areas of contention in this dispute was whether either of the drug makers faced irreparable harm. Amgen argued that it would suffer "irreversible price erosion" if ZARXIO® sales commenced. On the other hand, Sandoz claimed that its "head start" on other prospective makers of Neupogen® biosimilars, which is the key incentive in the biosimilar pathway, would be unfairly shortened or eliminated by an injunction.

While the Federal Circuit was apparently more sympathetic to Amgen's concerns, the order did indicate that Amgen may be required to post a bond that will compensate Sandoz on a daily basis if it turns out that ZARXIO® sales shouldn't have been delayed. The Circuit court order indicates that the parties are directed to file pleadings "concerning what amount of a bond, if any, should be posted *for each day* that the injunction is in place." (emphasis added).

The size of the daily bond will be the next biosimilar battleground. Neupogen® sales in the U.S. for the fourth quarter of 2013 alone were over $229 million. Needless to say, Sandoz will likely demand that Amgen post a very sizable bond for each day that it is enjoined. The Circuit court will determine the amount of the bond in a subsequent order.

Oral arguments on the injunction are set for June 3.

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