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Victories Over Amgen Bring Sandoz Closer to Launching First U.S. Biosimilar

By Philip Merksamer, J.D. Candidate 2017 | April 8, 2015

On March 6, 2015, the FDA approved Zarxio, a biologic pharmaceutical produced by Novartis' generic drug unit—Sandoz—that is biosimilar to Amgen's Neupogen. Now, after overcoming two important challenges, Sandoz is poised to bring the first biosimilar approved under the Affordable Care Act to the U.S. market.

Biosimilars are approximate copies of biologics—complex biologically based therapeutics produced in living cells. Analogous to the relationship between generic and brand name drugs, biosimilars are expected to have substantially similar efficacy and safety profiles to their brand name counterparts but at significantly lower costs.

In contrast to generics, biosimilars have mostly failed to penetrate the U.S. market due in part to a lack of a cost-effective regulatory and approval process. As a result, makers of biologics have enjoyed minimal competition even after losing patent exclusivity. A provision in the Affordable Care Act, called the Biological Price Competition and Innovation Act (BPCIA), addressed this issue by creating an abbreviated regulatory scheme for FDA approval of biosimilars in the U.S.

After the FDA approved Zarxio, Amgen filed a FDA citizen's petition and a lawsuit in federal court against Sandoz seeking an injunction to block the sale of Zarxio. Amgen argued that Sandoz failed to comply with a provision of the BPCIA requiring Sandoz to share its biosimilar application with Amgen, so that any potential instances of patent infringement could be identified and resolved. District Judge Seeborg, however, rejected Amgen's argument, ruling that compliance with this BPCIA provision is optional. The judge also ruled in Sandoz's favor on a notice provision that will provide Sandoz with an accelerated path to commercialization.

In addition, the FDA denied Amgen's citizen's petition, stating that the patent exchange provisions of the BPCIA are separate from FDA review. Together, these rulings remove some procedural barriers to bringing biosimilars to market.

The litigation is not yet over as Amgen has appealed to the Federal Circuit, with oral arguments expected in June. Ironically, Amgen has announced plans to produce at least nine biosimilars and a loss at the Federal Circuit may speed the regulatory path for Amgen's own biosimilars.