CLIENT ALERT

District Court's Decision Paves the Way for the First U.S. Biosimilar

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On Thursday, March 19, 2015, a district court ruling paved the way for the first biosimilar product approved by the U.S. Food and Drug Administration (FDA) to enter the market. Judge Seeborg in the Northern District of California granted a victory to Sandoz in its fight with Amgen, Inc. over Zarxio, Novartis AG's generic version of Amgen Inc.'s cancer drug Neupogen® (the "reference product") by denying Amgen's request for a preliminary injunction. In the order, the court sided with Sandoz on its interpretation of the portion of the Biologics Price Competition and Innovation Act (BPCIA) governing the disclosure requirements imposed on biosimilar manufacturers prior to sale of a biosimilar product. The 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. Amgen (the "reference product sponsor") has said that it will appeal the ruling.

The court's March 19 order in the battle between Sandoz and Amgen resolved two questions arising from the parties' conflicting interpretations of 42 U.S.C. § 262(l) of the BPCIA: (1) whether disclosure of a biosimilar applicant's Biologic License Application (BLA) and proprietary manufacturing information to the reference product sponsor is mandatory or permissive; and (2) whether a biosimilar applicant is required to give the reference sponsor 180-day notice of the first commercial marketing of the biosimilar only after the biosimilar is approved by the FDA. *Id.* at 3.

The Disclosure and Negotiation Procedures of 42 U.S.C. § 262 Are Permissive

42 U.S.C. § 262(l) "sets forth a process and timeline by which an applicant and reference product sponsor 'shall' participate in a series of information exchanges regarding potential disputes over patent validity and infringement." *Id.* at 4. As long as the parties continue to follow the procedures set forth in § 262(l), neither party is entitled to bring a declaratory action against the other regarding validity, enforceability, or infringement of any patents related to the reference product. *Id.*

Although the court acknowledged use of the term "shall" throughout the statute, it characterized the procedures set forth in § 262(l) as required only where the parties elect to take advantage of the benefits conferred by doing so. *Id.* at 9. Sections 262(l) and 35 U.S.C. § 271 set forth the consequences for noncompliance with the disclosure procedures set forth in § 262(l)—the reference product sponsor's right to immediately commence patent litigation. The court found that where, as here, Congress has specifically contemplated and provided a remedy for failure to comply with the disclosure procedures, such a failure to comply is not unlawful and is, therefore, permissive. *Id.* at 10-11.

The 180-Day Notice Provision Does Not Have to Occur After FDA Approval

The court also accepted Sandoz's interpretation of 42 U.S.C. § 262(l)(d) which requires that an applicant "shall provide notice to the reference product not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." Amgen argued that the term "licensed" in the statute indicated that the required 180-day notice must take place only after FDA approval is granted. *Id.* at 12. The court relied instead on the impact such a reading "would have on the overall statutory scheme;" specifically, that "Amgen's reading would tack an unconditional extra six months of market

exclusivity on the twelve years reference product sponsors already enjoy" under the statute. *Id.* at 13. If this had been Congress's intent, reasoned the court, it would have done so more explicitly. Therefore, the court found Sandoz's 180-day notice in advance of approval of its biosimilar version of Neupogen sufficient. *Id.* at 14.

Amgen had also argued that Sandoz's failure to comply with the disclosure and negotiation procedures of 42 U.S.C. § 262 and failure to give 180-day notice after approval of its BLA gave rise to claims under California's Unfair Competition Law (UCL) and conversion, as well as claims of patent infringement. *Id.* at 2. Sandoz responded that its actions were in line with the permissive nature of the statute, requiring the dismissal of Amgen's state-law claims and that noticed was allowed at any time 180 days prior to any commercial marketing of the biosimilar product, even prior to approval. *See id.* The court agreed with Sandoz on both counts.

As a result of its interpretation of the statute in Sandoz's favor, the court went on to dismiss Amgen's claims under the UCL and for conversion. *Id.* at 15. The court further held that Sandoz's counterclaims for invalidity and noninfringement were proper under the BPCIA and denied Amgen's motion for a preliminary injunction. *Id.* at 16-18. Sandoz had previously agreed to give Amgen five days' notice before launching its filgrastim product. *Id.* at 2 n.3.

The court's ruling, opens the doors for biosimilar manufacturers to avoid the extensive procedures set forth in 42 U.S.C. § 262(l) where an applicant for a biosimilar product "values expedience over risk mitigation," or "believe[s] that the disclosure and negotiation process would introduce needless communications and delay." *Id.* at 11. The ruling also clarifies that an applicant need not wait for approval to start the process under the BPCIA. Amgen has stated that it will challenge the ruling at the Federal Circuit.

As we reported earlier this month, Zarxio, developed by Novartis AG's Sandoz unit, was the first U.S. biosimilar approved by the FDA. The FDA found Zarxio to be highly similar to, but not "interchangeable" with, Neupogen®, which is designed to increase white blood-cell counts and lower infection rates, primarily in patients being treated for cancer. The designation as "highly similar" rather than "interchangeable" means that Zarxio cannot be substituted for Neupogen® without the intervention of the prescribing health-care provider, and only if permitted under relevant state law. The FDA further required Zarxio to be named "Filgrastim-sndz" after the active ingredient in Neupogen®, filgrastim.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

Terry Rea
Partner – Washington, D.C.
Phone: +1 202.624.2620
Email: trea@crowell.com

Keith J. Harrison
Partner – Washington, D.C.
Phone: +1 202.624.2560
Email: kharrison@crowell.com

James K. Stronski
Partner – New York
Phone: +1 212.895.4217

Email: jstronski@crowell.com

Anne Elise Herold Li
Partner – New York
Phone: +1 212.895.4279
Email: ali@crowell.com

Mary Anne Schofield, Ph.D.
Senior Counsel – Washington, D.C.
Phone: +1 202.624.2643
Email: mschofield@crowell.com

Pilar Stillwater
Counsel – San Francisco
Phone: +1 415.365.7444
Email: pstillwater@crowell.com