BRINKS GILSON & LIONE
100 YEARS OF IP LAW

THINK FORWARD

Biosimilar Product Notice

By James Sobieraj

July 13, 2016

The U.S. Court of Appeals for the Federal Circuit recently ruled in *Amgen Inc. v. Apotex Inc*. that a biosimilar-product applicant must give the reference product sponsor notice at least 180 days before commercially marketing and the 180-day period can only begin to run after the applicant receives FDA approval, even when the applicant complied with the so-called "patent dance" and exchanged patent information with the reference product sponsor pursuant to the BPCIA.

Apotex Inc. (Apotex) filed an application with the FDA, seeking permission to begin marketing a biosimilar version of Amgen's FDA-approved Neulasta®. Apotex then provided Amgen with a copy of the application and information on the manufacturing process, thereby launching the process for exchanging patent information and channeling patent litigation prescribed in the BPCIA (referred to many as the "patent dance"). Before obtaining FDA approval, Apotex notified Amgen of its future commercial marketing plans. After receiving such notification, Amgen filed an action for infringement. The district court preliminarily enjoined Apotex from entering the market until 180 days after FDA approval, rather than 180 days after the notice of commercial marketing was initially provided by Apotex.

The Federal Circuit affirmed. It rejected Apotex's argument that Apotex was not subject to the 180-day notice requirement because Apotex had complied with the "patent dance." The Federal Circuit confirmed that the 180-day notice was "mandatory and enforceable by injunction even for an applicant in Apotex's position." The court confirmed, furthermore, that the 180-day notice period will not begin until the biosimilar-product applicant receives the requested FDA approval. Referring to the BPCIA statute, the Federal Circuit found neither the plain language of the statute nor the litigation-focused purpose compelled a different interpretation. Also, the statute did not limit the application of the notice provision to circumstances where an applicant did not pursue the statutory information exchange process. Because the notice period starts only after receiving the requested FDA approval, the court explained that Apotex's pre-approval notice had no legal effect.

The Federal Circuit also addressed the argument that the mandatory notice would effectively extend the twelve-year exclusivity period given to the reference product sponsor by six months. The Federal Circuit noted the twelve-year date was established under 262(k)(7) of the BPCIA as an earliest date, not a latest date, and the extended period was consistent with the statute. Also, as time passes, the Federal Circuit noted that the extended period beyond twelve years would occur less frequently since more brand-name products would be newer and a biosimilar-product applicant would be able to file an application and request approval long before the 12-year period ends. Plus, the Federal Circuit suggested that the FDA may be able to approve biosimilar applications before the 12-year period ends with the caveat that the approval is only effective at the 12-year date, which could possibly eliminate any extension of the 12-year exclusivity period.

Contact Us

If you have any questions or wish to discuss how this decision impacts your business, please contact one of our Brinks Attorneys.