Biosimilar "Patent Dance" Does Not Permit Sidestepping of 180-Day Notice

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On July 5, 2016, the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) unanimously ruled in *Amgen v. Apotex* that biosimilar makers must provide brand-name rivals with a 180-day notice only after receipt of approval from the U.S. Food and Drug Administration (FDA), and that participation in the ?patent dance? does not change this requirement.

Apotex sought to market a biosimilar version of Amgen?s drug pegfilgrastim (Neulasta®), an anti-infective that stimulates production of a patient?s white blood cell count following chemotherapy. A ?biologic? is simply a medicinal preparation made from living organisms and their products. A ?biosimilar? is a biologic that is highly similar to an FDA-approved biologic, having no clinically meaningful differences in terms of safety and effectiveness. Following the guidelines provided in the Biologics Price Competition and Innovation Act of 2009 (BPCIA), Apotex and Amgen participated in the ?patent dance? ? a series of exchanges of information meant to streamline patent information. The information exchanged includes the biosimilar application and relevant manufacturing information for the biosimilar, patents held by the brand name company that may be infringed, and discussions regarding the validity and enforceability of those patents. Apotex raised the issue of whether the 180-day Notice of Commercial Marketing requirement of the BPCIA was mandatory and enforceable by injunction when a biosimilar applicant, such as itself, participated in the patent dance.

This case was first heard by the U.S. District Court for the Southern District of Florida, where the district court enjoined Apotex from entering the market unless it gave Amgen notice after receiving the FDA licensing and waiting 180 days. Apotex appealed this decision, but the Federal Circuit affirmed the district court?s grant of an injunction to Amgen, concluding that the 180-day Notice of Commercial Marketing requirement exists for all FDA-licensed biosimilar products, regardless of whether the biosimilar applicant participates in the patent dance. The Federal Circuit further rejected Apotex?s argument that the 180-day Notice of Commercial Marketing would unfairly extend the 12-year exclusivity period given to a brand name manufacturer by six months. Interestingly, the Federal Circuit stated, ?We have been pointed to no reason that the FDA may not issue a license before the 11.5-year mark and deem the license to take effect on the 12-year date.?

This suggestion likely will be the subject of further litigation, and perhaps future litigation against the FDA. Such litigation would address whether an early license issued prior to the 11.5 year mark is possible, whether or how the FDA might issue such a license, and what steps brand name companies can take to prevent the FDA from doing so.

Amgen Inc. v. Apotex Inc., No. 2016-1308 (Fed. Cir. July 5, 2016) ? Full text is available at: http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/16-1308.Opinion.6-30-2016.1.PDF.

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