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Court Rules that Apotex Must Give Amgen Notice Upon Biosimilar Licensure

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Since August 2015, Amgen and Apotex have been locked in litigation in the US District Court for the Southern District of Florida related to Apotex's pegfilgrastim product, which is purported to be biosimilar to Amgen's Neulasta®. As explained in a previous post, what is unique about this suit, is that Amgen brought suit after they and Apotex actually participated in the "patent dance" as set forth in 42 USC §§ 262(l)(2)-(5) of the Biologics Price Competition and Innovation Act (BPCIA).

On Wednesday, the Federal judge held that regardless of whether a biosimlar applicant participates in the patent dance, they must always provide 180 days notice of commercial marketing upon licensure to the reference product sponsor (RPS). The ruling was the first to address a key question left open by the Court of Appeals for the Federal Circuit's *Amgen v. Sandoz* decision regarding interpretation of the notice provisions of the BPCIA. While the Federal Circuit made clear that 180 day notice could only be effective upon licensure if the patent dance were bypassed, they seemed to suggest that notice might not be mandatory if biosimilar applicants comply with the patent dance.

In granting a preliminary injunction in favor of Amgen, Judge James I. Cohn held that notice upon licensure is in fact always mandatory. Judge Cohn stated that the BCPIA is intended to provide an orderly process for evaluating patent claims in the context of biosimilar products. Indeed the *Sandoz* court recognized that giving notice after FDA licensure, once the scope of the approved license is known and the marketing of the proposed biosimilar product is imminent, allows the RPS to effectively determine whether, and on which patents, to seek a preliminary injunction from the court. Requiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief. It provides a defined statutory window during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product. That defined statutory window exists for all biosimilar products that obtain FDA licenses, regardless of whether the biosimilar applicant complies with § 262(l)(2).

Two cases pending in other courts are likely to be affected by this ruling: *Janssen v. Celltrion* regarding biosimilar infliximab, and *Amgen v. Hospira* regarding biosimilar epoetin alfa. In addition to questions regarding how much disclosure is required by biosimilar applicants during the patent dance, both Celltrion and Hospira are challenging the 180 day notice.

Not surprisingly, Apotex has already appealed this ruling to the Federal Circuit.

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