Insights: Alerts

Amgen v Apotex - 180-Day Advance Notice of Biosimilar Marketing is Mandatory

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Written by

The Federal Circuit in July said in its Amgen-Sandoz decision that declining to share information under the biosimilars pathway "patent dance" made the 180-day advance-notice provision mandatory;[1] however, it left open the possibility that agreeing to share information made the 180-day advance-notice provision optional. This week a Florida Federal District Court judge slammed the door on this possibility for Apotex in its biosimilar application for Neulasta® (pegfilgrastim).[2] U.S. District Judge James I. Cohen found that notice is in fact always mandatory, concluding that optional compliance would "result in confusion and uncertainty, as well as inconsistent results, depending on which route a [biosimilar] applicant chooses to travel." This is the first post Amgen-Sandoz decision further interpreting the patent disputes resolution procedures under the Biologics Price Competition and Innovation Act (BPCIA). If the District Court's interpretation of the Affordable Care Act's biosimilars pathway stands, the 12-year marketing exclusivity granted to brand-name biologics under the BPCIA will be extended by six months. Thus, as some have argued,[3] resulting in a period of exclusivity longer than that intended under the BPCIA.

Under the BPCIA, a new biological product is granted 12-year marketing exclusivity from the date of first licensure during which rivals may not launch biosimilars. The Food and Drug Administration (FDA) will not accept biosimilar filings (351(k) filings) until five years after the original biologic is licensed. After the FDA has indicated acceptance of an application, a biosimilar applicant, at its discretion, may provide the reference product sponsor with information about its application, including detailed information about how the product is made. In response, the reference product sponsor would identify patent information under the patent dispute resolution procedures of the statute. This procedure, known as the "patent dance," sets up the first method in which patent litigation over a proposed biosimilar may be triggered under the BPCIA framework.

However, there may be necessary changes to the biosimilar and/or development process during the approval process that would potentially trigger new patent issues. To account for this, the BPCIA provides for the 180-day pre-marketing notice procedure as another opportunity to engage in patent litigation by permitting the reference product sponsor to seek a preliminary injunction before the biosimilar is marketed. The Federal Circuit has clearly said this 180-day notice can only be supplied after a biosimilar is licensed by the FDA.[4]

Many biosimilar applicants were hopeful that by opting to engage in the "patent dance" and any resulting patent litigation during the approval process, the biosimilar would not be required to provide the reference product sponsor 180-day notice of commercial marketing. As a result of the District Court's decision, if the FDA were to

approve Apotex's application for its pegfilgrastim product, Apotex will be required to provide Amgen with at least 180-day notice before the date of the first commercial marketing of the biological product licensed by FDA. Thus, Apotex is enjoined from "any commercial marketing of its biosimilar pegfilgrastim Product. . . . until Apotex gives Amgen proper notice, at least 180 days before first commercial marketing but not before its pegfilgrastim biosimilar product is licensed by the FDA, and the 180-day notice period is exhausted."

As expected, Apotex immediately filed a Notice of Appeal to the Federal Circuit.[5] We will continue to closely monitor any developments in this area, with the possibility still looming that a petition may be filed with the U.S. Supreme Court challenging the Federal Circuit's Sandoz-Amgen decision.

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[1] *Amgen Inc. et al. v. Sandoz, Inc.*, 794 F.3d 1347 (Fed. Cir. 2015).

[2] *Amgen Inc. et al. v. Apotex Inc. et al.*, Case No. 0:15-cv-61631, Order (S.D. Fla. Dec. 9, 2015).

[3] As noted by Mylan, Inc. in its Amicus Brief in Support of Sandoz's petition for Rehearing *En Banc*, "[t]he majority's interpretation distorts the statutory scheme, contradicts the plain language, and would produce "real world" outcomes contrary to Congress' intent. The consequences cannot be overstated: the majority interpretation would necessarily, in every case where notice is provided, extend the reference product's monopoly six months past the 12-year market exclusivity Congress granted. *See* 42 U.S.C. § 262(k)(7)(A). This exclusivity extension, implied from a simple notice provision, disrupts the statutory bargain and improperly delays competition." *Amgen, Inc. et al v. Sandoz, Inc.,* Case No. 15-1499*,* Brief of *Amicus Curiae* Mylan Inc. In Support of Defendant Appellee's Petition for Rehearing *En Banc* (Fed. Cir. Sept. 4, 2015).

[4] *Amgen*, 794 F.3d at 1358.

[5] *Amgen Inc. et al. v. Apotex Inc. et al.*, Case No. 0:15-cv-61631, Defendants Apotex Inc. and Apotex Corp.'s Notice of Appeal (S.D. Fla. Dec. 10, 2015).