Health Law Daily Wrap Up, DRUGS AND BIOLOGICS—Fed. Cir.: Biosimilar applicant must give 180-day post-licensure notice to reference sponsor, (Jul. 6, 2016)

Health Law Daily Wrap Up

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By Harold Bishop, J.D.

The Court of Appeals for the Federal Circuit decided that the statutory requirement that a biosimilar-product applicant give a post-licensure notice to the manufacturer of the original FDA-approved biologic (the reference product sponsor) 180 days prior to beginning commercial marketing is mandatory and enforceable by injunction. The court found that the post-licensure notice was required even though the biosimilar applicant gave notice to the reference product sponsor of its filing of an application with the FDA and abided by the statutory process for exchanging patent information with the reference product sponsor and channeling the patent infringement litigation (Amgen Inc. v. Apotex Inc., July 5, 2016, Taranto, R.).

Background. In 2002, Amgen Inc. received a biologics license from the FDA for Neulasta® (pegfilgrastim), a human-engineered protein for patients undergoing chemotherapy. In 2014, Apotex Inc. filed an application for an FDA license to market a biosimilar version of Neulasta®, invoking the abbreviated pathway for regulatory approval of follow-on biological products that are highly similar to a previously approved reference product. The abbreviated biosimilar pathway was allowed by the Biologics Price Competition and Innovation Act of 2009 (Biologics Act), which was created by sections 7001-7003 of the Patient Protection and Affordable Care Act (ACA) (P.L. 111-148).

Under the Biologics Act, a biosimilar-product application may not be submitted until four years after the reference product was first licensed by the FDA and a biosimilar-product license may not be made effective until 12 years after the reference product was first licensed. The Biologics Act also contains detailed requirements that are focused on ways to avoid or streamline potential patent litigation by requiring the exchange of patent information between the biosimilar-product applicant and the reference product sponsor after the FDA accepts the biosimilar-product application for review. Finally, the Biologics Act requires the biosimilar-product applicant to give notice to the reference product sponsor 180-days before commercial marketing of its FDA-licensed product.

After the FDA accepted Apotex’s application for review, Apotex and Amgen engaged in the exchange of patent information as required by the Biologics Act. After negotiations, the parties agreed to an action for infringement of two patents, but after one of the patents expired, Amgen’s patent infringement action against Apotex was only based on the one remaining disputed patent. This appeal, however, did not involve the infringement action but rather Amgen’s motion for a preliminary injunction to require Apotex to provide Amgen notice if and when it receives a license from the FDA and to delay any commercial marketing for 180 days from that notice.

Amgen v. Sandoz. Just before Amgen filed its patent infringement action against Apotex, the Federal Circuit decided the case of Amgen v. Sandoz (see Court interprets biosimilar ‘enigma’ in favor of abbreviated biologic license applicant, July 22, 2015). In Sandoz, the court held that the 180-day notice must be given after the FDA licensure of the biosimilar product, not before, and that the pre-licensure notice to the reference sponsor and the subsequent exchange of patent information are of no legal effect. Sandoz filed a petition for certiorari with the U.S. Supreme Court on February 16, 2016, seeking review of the Federal Circuit’s decision (see Reversal of fortune: Sandoz seek Supreme Court review in Amgen biosimilars battle, February 18, 2016).

Preliminary injunction motion. For purposes of the motion, the parties stipulated that Amgen will be irreparably harmed if Apotex enters the market without giving the requested 180 days’ notice, the balance of the hardships favors Amgen, and the public interest favors the issuance of an injunction. The decision whether to grant
the preliminary injunction motion, therefore, turned on whether the notice requirement is a mandatory one enforceable by injunction as to an applicant (such as Apotex) that, unlike Sandoz in *Amgen v. Sandoz*, gave the notice to launch the information-exchange process leading to the infringement suit.

**District court.** The U.S. District Court for the Southern District of Florida agreed with Amgen and granted a preliminary injunction. The court held that a biosimilar-product applicant must provide a reference product sponsor with a post-licensure notice 180 days before commercial marketing begins, regardless of whether the applicant provided the reference product sponsor notice of FDA review and began the patent information exchange process.

**Federal Circuit.** The Federal Circuit affirmed the district court’s grant of a preliminary injunction to Amgen. In *Amgen v. Sandoz*, the court held that the commercial-marketing provision is mandatory, with the 180-day period beginning only upon post-licensure notice, and that an injunction was proper to enforce the provision against Sandoz, a biosimilar-product applicant that had entirely skipped the statutory process of information exchange and patent-litigation channeling. Apotex argued on appeal that a different result was required here—that the commercial-marketing provision is not mandatory and may not be enforced by an injunction—because it, unlike Sandoz, did launch the statutory process for exchanging patent information and channeling patent litigation. The Federal Circuit rejected that distinction. It held that the commercial marketing provision is mandatory and enforceable by injunction even for an applicant in Apotex’s position.

The case is [No. 2016-1308](https://www.courtbot.org/fed-circuit/2016-1308).

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Companies: Amgen Inc.; Amgen Manufacturing Ltd.; Apotex Inc.; Apotex Corp.