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One More Hurdle Cleared – Amgen's Preliminary Injunction Motion for Filgrastim is Denied

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On March 19, 2015, Judge Seeborg of the United States District Court for the Northern District of California denied Amgen Inc.'s motion for a preliminary injunction in the *Amgen v. Sandoz* case, thereby removing one more hurdle for market entry of the first biosimilar in the United States. This current dispute hinges on the interpretation of two portions of subsection 42 U.S.C. § 262(l) of the Biologics Price Competition and Innovation Act.

Amgen initiated the current action on October 24, 2014, when it asserted that Sandoz acted unlawfully because it (1) failed to comply with subsection (l)'s patent disclosure and negotiation procedures (i.e., the "patent dance"); and (2) intends to market its biosimilar immediately upon receiving FDA approval, rather than waiting until at least 180 days thereafter. These actions, Amgen asserted, constitute the predicate wrongful behavior to sustain a claim under California's Unfair Competition Law. Amgen also asserted that Sandoz committed conversion by relying on Amgen's FDA license for Neupogen in its biosimilar application while failing to engage in the patent dance. For its part, Sandoz asserted that (1) biosimilar applicants may elect *not to provide* their applications to the reference product sponsor; (2) the BPCIA does not provide for injunctive relief, restitution, or damages for failure of a subsection (k) applicant to share its BLA; (3) the BPCIA sets forth exclusive consequences for failure to comply with 42 U.S.C. § 262(l)'s disclosure, negotiation, and notification provisions; (4) the BPCIA renders remedies under California's Unfair Competition Law and conversion claims unlawful and/or preempted; (5) a reference product sponsor does not maintain exclusive possession or control over its biologic product license; (6) noninfringement of Amgen's U.S. Pat. No. 6,162,427 patent; and (7) invalidity of the '427 patent. As outlined below, the court decided the issues regarding interpretation of the BPCIA sections in Sandoz's favor.

BPCIA – Notification and Negotiation Provisions Are Optional

Sandoz elected not to supply Amgen with a copy of its BLA and manufacturing process description within twenty days from notice that the FDA had accepted its application for review, and to engage in the patent exchange process set forth in subsection (l). Amgen argued that use of the term "shall" in this subsection required disclosure of Sandoz's BLA and forced the exchange process on the biosimilar applicant. The court agreed with Sandoz that subparagraphs (l) (9)(B) and (C) expressly contemplate the scenario in which an applicant opts not to comply with the disclosure procedures, or fails to follow through after having begun the process. Specifically, the court stated that these sections of the BPCIA allow the reference product sponsor to commence patent litigation immediately in either instance—thereby removing (or precluding) availability to the applicant of the 230-day litigation safe harbor provided by the patent exchange process. The court noted that Congress took the additional step in the BPCIA to amend 35 U.S.C. § 271(e) to add that an applicant's failure to disclose information regarding a potentially infringed patent under subsection (l)'s requirements is immediately actionable, making it clear that such a dispute is ripe for adjudication.

BPCIA - One Hundred Eighty Days' Notice Prior to First Commercial Marketing Need Not Await Licensure

The court also disagreed with Amgen that the correct interpretation of the statute required that an applicant must await licensure of the biosimilar before giving the required 180-day notice of commercial marketing to the reference product sponsor—resulting in a mandatory 180-day post-FDA approval waiting period prior to biosimilar market entry. The court pointed out that since the

FDA cannot license a biosimilar until twelve years after approval of a reference product, Amgen's reading would tack an unconditional extra six months of market exclusivity onto the twelve years reference product sponsors already enjoy under 42 U.S.C. § 262(k)(7)(A). In reaching this conclusion, the court expressly declined to follow a contrary interpretation reached in a prior decision of the same district court involving the same two parties

What's next?

Amgen has stated that it will appeal the decision of the court and both parties previously agreed to seek expedited review. In any event, Sandoz has promised to give Amgen five days' notice before launching its biosimilar. Although Amgen's motion for a preliminary injunction and state law claims were dismissed, Amgen's patent infringement claims are still outstanding, as are Sandoz's noninfringement and invalidity counterclaims. The decision also bodes well for Celltrion, which likewise declined to engage in the patent dance after filing its application for a biosimilar of Remicade and was recently sued by Janssen.

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