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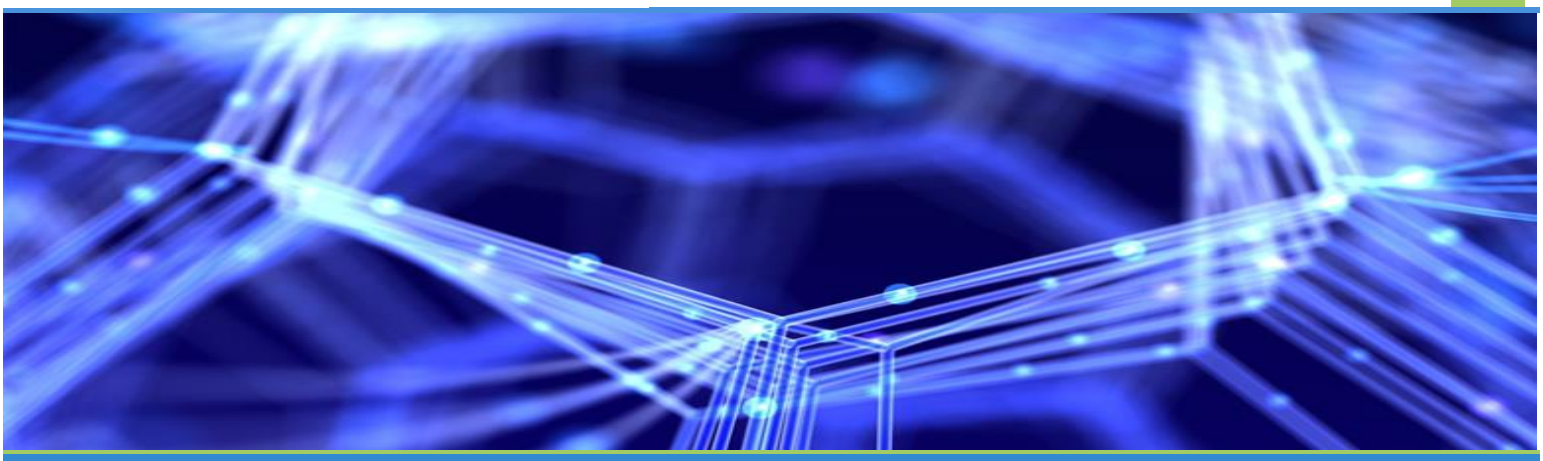

Intellectual Property Litigation | Alert

January 2017

Amgen Inc. v. Sandoz Inc. Expected to Clarify BPCIA Obligations

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) established an abbreviated approval process for biosimilar applications, but that process forces drug makers to navigate uncertain obligations for an applicant's disclosure of its application and notice of commercial marketing. On Jan. 13, 2017, the U.S. Supreme Court granted *certiorari* in *Amgen Inc. v. Sandoz Inc.* to hear arguments regarding the BPCIA's notice and disclosure requirements. Specifically, the Court will determine: (1) whether the BPCIA's disclosure requirements are mandatory for biosimilar applicants; and (2) whether the BPCIA's notice requirements effectively grant certain reference products an extended exclusivity period.

The case concerns Zarxio, Sandoz's biosimilar of Amgen's Neupogen and the first commercially available biosimilar approved under the BPCIA. Pursuant to subsection (k) of the BPCIA, codified at 42 U.S.C. § 262(k), Sandoz submitted an abbreviated Biologics License Application (aBLA) to the Food and Drug Administration (FDA) in July 2014. The BPCIA provides specific procedures for disclosure and negotiation between the applicant and the reference product sponsor (RPS), including that subsection (k) applicants "shall provide" the RPS with the aBLA and manufacturing information in Section 262(l)(2)(A), as well as notice "not later than 180 days before the first commercial marketing of the biological product licensed" in Section 262(l)(8)(A). The parties disagreed on how to interpret these provisions, and Amgen filed suit in the Northern District of California based on alleged violations of subsection (l).

In response to Amgen's allegations of unfair competition, conversion, and patent infringement, Sandoz counterclaimed for a declaratory judgment adopting its interpretation that the BPCIA: (1) does not require a subsection (k) applicant to disclose its aBLA and manufacturing information to the reference product sponsor; and (2) allows an applicant to give effective notice of commercial marketing prior to FDA approval. The district court granted Sandoz judgment on the pleadings and dismissed Amgen's non-patent claims. Amgen appealed to the Federal Circuit.

Writing for a divided panel, Judge Lourie concluded that the district court had correctly interpreted Section 262(l)(2)(A)'s disclosure requirement but erred with respect to notice under Section 262(l)(8)(A). The court focused on the fact that the BPCIA specifies remedies—namely, patent litigation—for failure to timely disclose the aBLA and manufacturing information, but has no similar provision for inadequate notice of commercial marketing. Accordingly, the court

determined that applicants are not required to meet Section 262(l)(2)(A)—remedy provisions would be superfluous otherwise—but must satisfy Section 262(l)(8)(A) before marketing.

Relying on Section 262(l)(8)(A)'s use of the term "licensed," the Federal Circuit further reasoned that an applicant can only market its biosimilar if it has provided sufficient notice after the product has been licensed by the FDA. Addressing Sandoz's concern that this would unconditionally and improperly extend a given reference product's exclusivity beyond the 12 years granted under Section 262(k)(7)(A), the majority dismissed the issue as limited to the unusual circumstance—present in this litigation—where the first aBLA for a given reference product is not filed until after expiration of the statutory grant.

Both parties petitioned for *certiorari*, and the Solicitor General recommended that the Supreme Court review both issues. In its brief, the Solicitor General largely supported Sandoz on both provisions, arguing that subsection (k) applicants are not required to provide information under Section 262(l)(2)(A) and that pre-licensure notice is sufficient for Section 262(l)(8)(A), injunctive relief being unavailable. While it remains to be seen whether the Supreme Court will agree, biosimilar applicants can expect much-needed clarity regarding their BPCIA obligations.

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