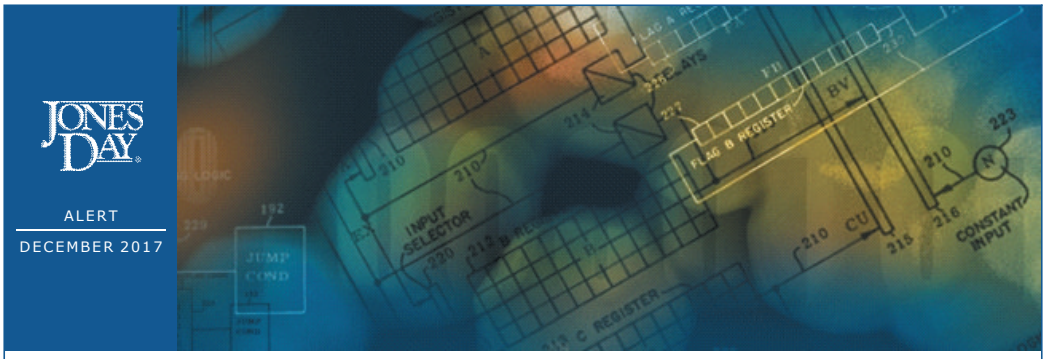

Federal Circuit Rules BPCIA Preempts State Law

On December 14, 2017, the U.S. Court of Appeals for the Federal Circuit again interpreted the Biologics Price Competition and Innovation Act ("BPCIA"). In *Amgen Inc. et al. v. Sandoz Inc.*, 15-cv-1499 (Fed. Cir. 2017), the Federal Circuit sided with Sandoz in ruling the BPCIA preempts state law remedies for noncompliance with 42 U.S.C. § 262(*l*)(2)(A) ("patent dance"). This case was decided on remand from the recent Supreme Court ruling in *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664 (2017), which held that federal injunctions are not available to compel "patent dance" disclosures. On remand, the Federal Circuit was asked to decide whether noncompliance with the patent dance requirements could violate California state law.

Under the BPCIA, an applicant filing an abbreviated biologics license application ("aBLA") typically must submit information to demonstrate its proposed product is a "biosimilar" to the approved reference product. The BPCIA requires an applicant to disclose its aBLA and manufacturing information to the reference product sponsor ("RPS") no later than 20 days after the FDA accepts an aBLA for review. The Supreme Court ruled that the exclusive remedy available to an RPS under federal law for an applicant's failure to meet its patent dance obligations was filing an immediate infringement action against the biosimilar applicant.

At issue was whether Sandoz's nondisclosure of its aBLA and manufacturing information for its biosimilar of Neupogen® was sanctionable under California's unfair competition law. In a unanimous decision, the Federal Circuit held:

- The BPCIA preempts all state law claims predicated on an applicant's failure to comply with § 262(*l*)(2)(A). According to the Federal Circuit, "The field here is biosimilar patent litigation, not patent law generally … the federal government has fully occupied this field." Moreover, state law remedies "clash" with the BPCIA and would "'dramatically' increase the burdens on biosimilar applicants beyond those contemplated by Congress."
- BPCIA § 262(*l*)(9)(C) permits the RPS to bring an action for a declaration of infringement, validity or enforceability. This is the exclusive remedy for noncompliance with § 262(*l*)(2)(A). Federal law and state law do not permit injunctive relief, damages, or sanctions for noncompliance.

This case underscores the limited remedies available to an RPS for a biosimilar applicant's failure to comply with its patent dance disclosure obligations. The Supreme Court ruling in *Sandoz* held that federal injunctions are not available to compel disclosure. The Federal Circuit has now held that state law remedies also are not available. Thus, the only option for innovator companies in Amgen's situation is to bring an immediate infringement suit and seek the aBLA and manufacturing information through discovery.

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