IP News Alert

FEDERAL CIRCUIT DECIDES THAT STATE LAW IS PREEMPTED BY BIOSIMILAR ACT IN *AMGEN V. SANDOZ*

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- The Federal Circuit held that the Biologics Price Competition and Invention Act of 2009 (BPCIA) provides the exclusive remedy for failure to comply with its disclosure requirements.
- Because the BPCIA preempts state law claims, Amgen cannot obtain injunctive relief or damages for biosimilar applicant Sandoz' failure to disclose required information.
- Since this preemption issue presents "a significant question of general impact or of great public concern" that had been fully briefed, the court determined that the preemption defense had not been waived.

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The Court of Appeals for the Federal Circuit (Federal Circuit) held that state law claims made by Amgen against Sandoz in the Northern District of California were preempted by the BPCIA. The BPCIA provides an abbreviated pathway for regulatory approval of a biological product that is "highly similar" to a previously-approved product ("reference product"). It establishes a process for information exchange, between the biosimilar applicant and the reference product sponsor, under which the biosimilar applicant provides a copy of its application and its product manufacturing information to the reference product sponsor.

Amgen markets filgrastim under the brand name NEUPOGEN®. Sandoz filed an application seeking FDA approval of a biosimilar filgrastim product, but it did not disclose its application or its product's manufacturing information to Amgen. Amgen sued Sandoz, asserting unfair competition claims by engaging in unlawful business practices under California Business & Professions Code (UCL) and conversion.

On remand from the Supreme Court, the Federal Circuit held that differences in remedies between the "federal scheme and state law claims" bar Amgen's state law claims. Otherwise, according to the Court, application of the regulatory regime of the BPCIA would be conducted "in the shadow of the 50 States' tort regimes," and would "'dramatically increase the burdens' on biosimilar applicants beyond those contemplated by Congress in enacting the BPCIA."

Despite the fact that Sandoz did not present a defense of preemption before the district court, the Federal Circuit held that it had discretion to address the issue, relying on the Supreme Court's "express" invitation to the Federal Circuit to address preemption and "to [assume] that a remedy under state law would exist if there were not preemption." Noting that the preemption issue presents "'a significant question of general impact or of great public concern'" that had been fully briefed, the Court determined that Sandoz had not waived its preemption defense.

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The Court stated that, "where, as here, 'Congress made a deliberate choice not to impose' certain penalties for noncompliance with federal law, state laws imposing those penalties 'would interfere with the careful balance struck by Congress.'"

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