



In The Press: IPWATCHDOG Turns to Partner Charles R. Macedo for his Insights on SCOTUS decision in Sandoz v. Amgen over Biosimilar Drugs

Industry Reaction to SCOTUS decision in Sandoz v. Amgen

By Gene Quinn



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In *Sandoz v. Amgen*, the Supreme Court addressed the “plain language” of a “carefully crafted and detailed enforcement scheme” relating to “biologic” drugs. Under this complex statute that was enacted as part of ObamaCare as an effort to get generic biosimilar and interchangeable biologic drugs on the market quicker if the patent hurdle can be overcome. In a unanimous decision, the Supreme Court vacated, reversed and remanded yet another Federal Circuit decision. Even when the Supreme Court agreed with part of the result arrived at by the Federal Circuit, the Court nevertheless felt obliged to explain why the Federal Circuit had the wrong reason for the correct result.

By rejecting the availability of injunctive relief to enforce a violation of the statutory provisions, some might argue that the Court gutted the protections provided by Congress in reaching the carefully crafted compromise. However, the Court nevertheless offered a few rays of hope. In footnote 2, when it “express[ed] no view” on an alternative theory on which an injunction might issue under a different provision for this same violation of the statute. The Court also



remanded for potential resolution under state law. The answer to these questions will no doubt be left unresolved by the Court for many more years.

Finally, it is worth mentioning that Justice Breyer's concurrence is a foreshadowing of the battle we can expect to see next year (in SAS) over the continuing viability of the *Chevron* doctrine.

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