

## Supreme Court Will Judge Biosimilar Patent Dance

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The **U.S. Supreme Court** has agreed to review some of the patent dispute resolution provisions of the **Biologics Price Competition and Innovation Act (BPCIA)**. The Court [granted certiorari](#) in the dispute between **Amgen** and **Sandoz**, where the [Federal Circuit decided](#) that the biosimilar patent dance provisions are optional, but pre-marketing notice always is required.

### Do Biosimilar Applicants Have To Join In The Patent Dance?

Amgen's March 21, 2016 [conditional-cross petition for certiorari](#) asked the Court to decide the following issue:

Is an Applicant required by 42 U.S.C. § 262(l)(2)(A) to provide the Sponsor with a copy of its biologics license application and related manufacturing information, which the statute says the Applicant "shall provide," and, where an Applicant fails to provide that required information, is the Sponsor's sole recourse to commence a declaratory-judgment action under 42 U.S.C. § 262(l)(9)(C) and/or a patent-infringement action under 35 U.S.C. § 271(e)(2)(C)(ii)?

### Do Biosimilar Applicants Have To Wait For Approval

#### To Give Pre-Marketing Notice?

Sandoz's February 16, 2016 [petition for certiorari](#) asked the Court to decide the following issue:

Whether notice of commercial marketing given before FDA approval can be effective and whether, in any event, treating Section 262(l)(8)(A) as a standalone requirement and creating an injunctive remedy that delays all biosimilars by 180 days after approval is improper.

### Will The Court Follow The Solicitor General's Lead Or Be Swayed By Amici?

As reported in [this article](#), the Solicitor General of the United States filed an *amicus* brief that sided with Sandoz on both issues. In particular, the Solicitor General thinks the Federal Circuit correctly held that the information exchange provisions of 42 USC § 262(l)(2)(A) are optional, but does not agree that the pre-marketing notice required by 21 USC § 262(l)(8)(A) cannot be given until the biosimilar product has been approved by the FDA.

The Court has granted Apotex's motion to file an *amicus* brief, and it is likely that other stakeholders on both sides of the issues will want to make their views known to the Court.

These articles discuss previous proceedings in *Amgen v. Sandoz* and explain the biosimilar patent dance issues in more detail:

- [The district court decision in \*Amgen v. Sandoz\*](#)
- [The Federal Circuit decision in \*Amgen v. Sandoz\*](#)
- [The Sandoz petition for \*certiorari\*](#)
- [The Amgen opposition and conditional cross-petition for \*certiorari\*](#)
- [The Solicitor General's \*amicus\* brief](#)

If the Court follows its usual schedule, the case will be argued this spring and a decision will be rendered by the end of the Court's current term in June.

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