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No Rehearing Of Biosimilar Patent Dance Decision

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The Federal Circuit denied the petitions for rehearing *en banc* filed in ***Amgen Inc. v. Sandoz Inc.***, which was the court's first decision interpreting the ***Biologics Price Competition and Innovation Act (BPCIA***). Perhaps the court thought that because both parties sought rehearing they must have gotten it right, but Amgen and Sandoz took issue with different aspects of the panel decision.

The Panel Decision Interpreting the BPCIA

As summarized in this article, the panel decision *Amgen Inc. v. Sandoz Inc.* interpreted several aspects of the BPCIA related to patent dispute resolution and market entry. In the portion of the decision Amgen disagreed with, the panel held that a biosimilar applicant does not have to share its biosimilar application with the reference product sponsor or follow the patent dispute resolution procedures set forth in the BPCIA. In the portion of the decision Sandoz disagreed with, the panel held that a biosimilar applicant must give 180 days' pre-marketing notice to the reference product sponsor and cannot do so until after the FDA has "licensed" (approved) the biosimilar product.

The Future Of The Biosimilar Patent Dance

The full court's decision to deny rehearing was made despite *amicus* briefs filed by the Biotechnology Industry Organization, Abbvie Inc. and Janssen Biotech, Inc., who each urged that the patent dispute resolution procedures of the BPCIA should be mandatory. (You can read more about the *amicus* arguments here.) While both Amgen and Sandoz may pursue petitions for *certiorari* at the Supreme Court, it is not clear that the Court will want to get involved this early in the statute's provenance.

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