June 12, 2017

# *The Patent Dance Is Optional*

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In *Sandoz Inc. v. Amgen Inc.*, the Supreme Court brought greater certainty to two key issues relating to the "patent dance" under the Biologics Price Competition and Innovation Act (BPCIA). **First**, the Court held that where a biosimilar applicant declines to provide its application and manufacturing information, the patent owner's exclusive remedy under federal law is to bring a declaratory judgment action for patent infringement. The Court left open for now whether a patent owner may have additional remedies under state law. **Second**, the Court held that a biosimilar applicant may provide its mandatory 180-day notice of commercial marketing at any time and need not wait until FDA has approved its application.

Today's decision means that a biosimilar applicant can elect not to provide the reference product sponsor with access to its application and manufacturing information. And, as a consequence, this also provides the option to not participate in the resulting exchange of patent information provided for under the BPCIA—commonly referred to as the "patent dance." The sole remedy available to the reference product sponsor under federal law is to file a declaratory judgment action for patent infringement.

Whether future biosimilar applicants elect to participate in the patent dance will likely depend on whether they see a strategic benefit to the early exchange of product and patent information in a given case. If not, today's decision gives little incentive for them to do so.

The most consequential aspect of today's decision is the Court's conclusion that a biosimilar applicant may give its 180-day notice of intent to commercially market before it receives FDA approval. This means that, absent a court injunction, a biosimilar applicant will be free to market its product immediately upon FDA approval so long as it provided its notice at least 180 days prior to FDA approval.

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